Submitter : **Dr. Michael Ruckenstein** **Date: 09/15/2005**

Organization : **University of Pennsylvania**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I am discouraged and dismayed by the CMS proposal to reduce reimbursement for cochlear implant procedures and devices. The cochlear implant is a true medical miracle. It is currently the only prosthesis that restores any of the 5 human senses. It restores recipients with severe to profound hearing loss to a meaningful and productive lifestyle that would otherwise be restricted by their hearing loss. It allows these patients, particularly the elderly, to maintain an independent lifestyle and often allows them to avoid being placed in a care facilty. Benefits of the cochlear implant extend beyond the patients to their caregivers, who no longer have to loose as many work hours to look after the needs of their hearing compromised dependents. These benefits are not merely anecdotal. They have been documented in some of the most extensive scientific literature that has been published over the past decade.
It is critical that patients receiving medicare benefits continue to be allowed to receive the benefits of cochlear implants. Not to provide them these benefits would cost society in terms of long-term financial outlay and deny patients significant improvements in their quality of life.
I respectfully request that CMS substitute accurate external device cost data and recalculate the relative weight of APC 0259. If CMS is unable to comply with this request, I request that the 2006 OPPS payment be no lower than 100% of the 2005 payment plus the inflation and update factors.

Many thanks for consideration of this request.

Michael J. Ruckenstein M.D., M.Sc, FACS
Associate Professor
Department of Otorhinolaryngology, Head and Neck Surgery
University of Pennsylvania
Philadelphia, PA 19104

Submitter : Ms. Michele Corey **Date:** 09/15/2005

Organization : Henry Ford Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Ms. Mary Whitbread

Date: 09/15/2005

Organization : Henry Ford Health System

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1501-P-452-Attach-1.DOC

Mary Whitbread, Vice President
Reimbursement and Contracting
One Ford Place
Detroit, Michigan 48202

Ph: (313) 874-9533
Fax: (313) 876-9229

September 15, 2005

Dr. Mark McClellan, Administrator
Centers for Medicare & Medicaid Services
Department for Health and Human Services
Attention: CMS-1427-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: CMS-1501 - P — Medicare Program; Changes to the Outpatient Prospective Payment System and 2006 Rates; Proposed Rule, July 25, 2005 *Federal Register*

Dear Dr. McClellan:

On behalf of the Henry Ford Health System, we appreciate the opportunity to provide input on the proposed rule for the 2006 Medicare Outpatient Prospective Payment System, published in the July 25, 2005 *Federal Register*. We do have significant concerns regarding some of the proposals and hope you will take our comments into consideration.

The hospitals within the Henry Ford Health System are gearing up for a very difficult year in 2006, given substantial cuts in the other governmental programs and the growing number of uninsured patients. The changes proposed in Medicare's outpatient program are very troubling because they contain unanticipated cuts to an already under-funded sector of our business. We hope our comments will receive due consideration because we believe they serve to make the OPPS a more equitable payment system.

Multiple Diagnostic Imaging Procedures

(Federal Register pages 42748-42751)

We are very concerned about the proposal to decrease the payment for multiple imaging procedures. We agree that the cost of obtaining an additional image, within the same family and during the same encounter is somewhat lower than the cost of the initial image. A corresponding reduction in payment might be appropriate under a payment system that uses discrete procedural costing, such

as RBRVS. We would argue strongly, however, that it is not appropriate to apply these reductions under OPPS. Because OPPS uses aggregate departmental costs in determining the payment level, payments already reflect the lower costs of additional images. To apply a further reduction would result in aggregate payments for this category of services that are substantially below aggregate costs. We believe this is contrary to the statute.

The oversight in the proposal stems from the fact that hospitals do not generally reduce their charges for additional images. Within a given "family" the charges are generally a uniform per image charge. Because the charge is the same for both the initial and additional images, the costs allocated to each is the same, reflecting the weighted average costs of doing single and multiple images. When the APC amount for a given family was calculated, even though only single procedure claims were used, the CCR converts the claim to this weighted average cost, as opposed to the true cost for the initial image.

To show how this impacts aggregate payments, let's assume a CT department does 2,000 "family 2" scans, for a total cost of $410,000. With a unit charge of $500 per test, charges would total $1,000,000 and the overall CCR for the department would be 41% ($410,000/$1,000,000). The mean cost per test would be $205 using this CCR of 41% ($500 x .41). This is the amount that CMS would use to calculate the base APC payment amount. On claims for two images, the total charges would be $1,000 and the calculated mean cost would be $410 ($1,000 x .41), or twice the cost of one test. This, as indicated in Section 1 of Attachment 1 is reflective of the current method of uniform payments for each image.

We can model the proposed impact of the multiple image reduction on a hospital for "family 2 CT scans" using average cost data from the CMS median cost file (the $205 used in attachment 1 as the mean cost) and using the ratio of multiple to single image claims for "family 2 CT scans" as reported by CMS in the proposed rule (1.1 million of 2.7 million claims or 41% were for multiple images). Using that ratio, a CT department doing 2,000 images would, on average, have about 1,350 encounters/claims. About 800 of the encounters would be for single images. The remaining 550 encounters would involve two or three images for a total of 2,000 images. If we break the data down to show the impact of the proposal (Section 2 of attachment 1), we can see the aggregate payment to cost ratio goes down significantly, which we believe is contrary to statute and CMS intent.

The problem again lies in the fact that aggregate costs are spread evenly to single and multiple image services by virtue of the charge policies. Section 3 shows what would happen if hospitals reduced the charge for additional images, under the assumption an additional image costs 50% less. Total costs do not

change, since these reflect a hospital's actual costs. Total charges would decrease, however, resulting in a higher CCR. This would increase the mean cost for the initial image by 19%. Since this is an issue that is universal for hospitals, and the data reflects actual national mean costs and multiple image volumes, it would result in a corresponding increase in the APC payment amount for the initial image. This increase would maintain an aggregate payment to cost ratio that would be consistent with the other APCs.

We strongly recommend that CMS either continue to pay additional images at the full APC amount or that an adjustment be applied to the median cost data. We believe to implement this proposal as presented would violate section 1833(t)(2)(C) of the BBA 1997, since it would result in aggregate payments well below average hospital costs. It would also make the impacted APCs big losers for hospitals, potentially limiting access for Medicare beneficiaries.

Drug Administration

(Federal Register pages 42724-42728)

We support CMS in the effort to utilize CPT coding whenever possible in the hospital setting and to promote consistent, uniform coding regardless of the setting. In the case of drug administration, however, we feel the CPT codes are unduly complex. Our coding and nursing staffs have reviewed the new codes and are extremely concerned with the complexity and administrative burden they pose. We strongly urge CMS to delay the implementation of the new codes pending review by the APC panel and/or hospitals with large cancer programs.

Non-Pass Throughs: Proposed Payment for Specified Covered Outpatient Drugs

(Federal Register pages 42724-42728)

The proposed payments for drugs at a level of the ASP +6% results in payments that are below our acquistion costs for several expensive and frequently used drugs. Payments remain below acquistion costs even when increased to the ASP +8% to factor in handling costs. We urge CMS to gather further data on the following drug costs in particular:

J9170	Docetaxel
J2353	Octreotide injection, depot
J9305	Pemetrexed injection
J7317	Sodium hyaluronate injection
J1745	Infliximab injection

J9206	Irinotecan injection
J9185	Fludarabine phosphate inj
C9205	Oxaliplatin

These drugs are paid at a rate below our acquisition costs.

Non-Pass-Throughs: MedPAC Report on APC Payment Rate Adjustment of Specified Covered Outpatient Drugs (*Federal Register pages 42728-42731)*

We believe the payment adjustment proposed to pay for the handling costs for drugs is extremely inadequate. In our hospital pharmacy, which handles about $63 million in drugs. The salary and benefits alone for that department total $8.6 million, or 12% of the total costs. Further "handling" costs are incurred when the drugs reach the nursing areas.

We also believe that, because the pharmacy is allocated indirect expense on the cost report, the drug payments need to cover these costs as well. Otherwise, hospitals with a higher than average outpatient drug program are not recouping indirect costs at the same rate as other hospitals.

Finally, while we see the usefulness to CMS in collecting claims data and charges for the drug handling costs, this reporting requirement would overwhelm our coding and nursing staffs. Coding for the increasingly complex drug administration fees, as well as the complexity of insuring the correct dosage is billed, is a big enough challenge already. We think CMS would get more accurate information by surveying hospital pharmacy departments and studying data on the departmental costs of hospital pharmacies.

Device Dependent APCs (*Federal Register pages 42713-42721)*

We urge CMS to reevaluate the methodology used to calculate median costs for device dependent APCs. Payment has been below costs for these services since the pass-through payments were eliminated, and the problem grows bigger each year. While the trended median costs show a significant decline, our acquisition costs for devices have generally increased over the last several years.

Of particular concern are the proposed rates for cardiac defibrillator implants. As these devices get more technologically advanced, they are getting more expensive. Our average supply costs this year, for the defibrillator without leads (APC 107), are $24,700 and the current payment is only $17,963. The proposed rule reduces the payment to $15,362. With leads, our costs climb to an average of $29,400. The 2005 payment is at $24,121, reduced to $20,629 in 2006. When the non-supply costs are added in, our loss for a defibrillator with leads will be almost $12,000 per case under the proposed rates.

We have no problems with the APC Panel recommendations to convert defibrillator claims to single procedure claims (as discussed on page 42716). In theory, we agree with assumptions made. We think the problem lies in the cost to charge ratio being used to convert the device charges to costs. We think most hospitals use a much lower mark-up on these expensive devices than they do for supplies in general.

Cost Outlier Payment Thresholds

(*Federal Register* pages 42701- 42702)

We have concerns with CMS' proposal to reduce aggregate outlier payments to 1 percent of total payments under the outpatient prospective payment system ("OPPS"). To ensure that total outlier payments do not exceed this targeted percentage, CMS has proposed to raise the outlier threshold to $1,575 (70 Fed. Reg. at 42701). Yet, CMS has offered no data supporting the accuracy of this proposed threshold. Indeed, CMS has never published any information concerning whether any of its prior outpatient outlier formulas have ever resulted in the targeted payment amounts. This absence of information stands in stark contrast with CMS' inpatient rulemaking, in which CMS routinely informs the provider community regarding whether it had properly used the full amount set aside for outlier payments. CMS has previously received comments regarding the need to publish outpatient outlier data regarding prior year set asides. 69 Fed. Reg. 65682, 65846 (Nov. 15, 2004).

Based on our own experience, we suspect the CMS model is deficient. Our 2005 outlier rate is 1.6% of our total payments and, while we understand that any individual hospital's experience may vary from the target outlier payment amounts, we are a large system with sick patients and above average use of cutting edge technologies. If our outpatient outlier payments have not reached at least 2 percent, we strongly doubt that CMS' model for projecting outlier payments is accurate.

We would also urge that, in order to reach the targeted outlier pool, CMS pay outpatient claims at the same rate at which inpatient outlier claims are paid: 80% of costs. This will ensure hospitals can recoup, at a minimum, the variable costs of providing expensive care.

Teaching Hospital Impact

Major teaching hospitals yet again show payments changes well below those of other hospitals according to the proposed rule. We urge CMS to review the trend in payments to teaching hospitals to determine if hospitals are adequately

reimbursed for IME costs incurred in the outpatient setting. While CMS has historically argued that OPPS reimburses separately for the higher costs of IME in the outpatient setting, that is true only for additional ancillary services. Teaching hospitals are not adequately reimbursed for major costs including significantly longer operating room times.

Thank you for your consideration of our comments. If you have any questions or we can provide further information, I can be reached at (313) 874-9533 or you can email me at **mwhitbr1@hfhs.org**.

Sincerely,

Mary Whitbread
Vice President, Reimbursement and Contracting

Payments for Multiple Images
Impact on the Aggregate Payment to Cost Ratio

Section 1: Current Method:

	# Scans	# of Encounters/ Claims	Charge	Charges	Costs	CCR	Mean Cost per Median Cost File	APC Payment Per Scan	Total Payments	Margin	Payments as a % of Costs
CT Dept	2,000	1,350	500	1,000,000	410,000	41.0%	205.00	193.00	386,000	(24,000)	94%

Section 2: CMS Proposed Method - Reducing Payment for Multiple Imaging Procedures by 50%

	# Scans	# of Encounters/ Claims	Unit Charge	Total Charges	Calculated Costs	CCR	Mean Cost per Median Cost File	APC Payment per Encounter	Total Payments	Margin	Payments as a % of Costs
Single Image	800	800	500	400,000	164,000	41.0%	205.00	193.00	154,400	(9,600)	94%
Two Images	900	450	1,000	450,000	184,500	41.0%	410.00	289.50	130,275	(54,225)	71%
Three Images	300	100	1,500	150,000	61,500	41.0%	615.00	386.00	38,600	(22,900)	63%
Total	2,000	1,350	500	1,000,000	410,000	41.0%	205.00	161.64	323,275	(86,725)	79%

Section 3: Impact on Mean Cost if hospitals charged 50% less for additional images

	# Scans	# of Encounters/ Claims	Charge	Charges	Calculated Costs	CCR	Mean Cost	APC Payment per Encounter	Total Payments	Margin	Payments as a % of Costs
Single Image	800	800	500	400,000	195,821	49.0%	244.78	230.45	184,358	(11,463)	94%
Two Images	900	450	750	337,500	165,224	49.0%	367.16	345.67	155,552	(9,672)	94%
Three Images	300	100	1,000	100,000	48,955	49.0%	489.55	460.90	46,090	(2,866)	94%
Overall Average	2,000	1,350	419	837,500	410,000	49.0%	205.00	193.00	386,000	(24,000)	94%

Addendum 1

Submitter : Dr. Henry Wise, II

Date: 09/15/2005

Organization : AKSM, Ltd.

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1501-P-453-Attach-1.PDF

AKSM
State-of-the-art care, delivered when you need it.

September 16, 2005

VIA ELECTRONIC SUBMISSION

Mark McClellan, M.D., Ph.D. Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule
CMS-1501-P
"New Technology APCs" and "New Procedure Codes"

Dear Dr. McClellan:

On behalf of American Kidney Stone Management, Ltd. ("AKSM"), we are pleased to submit comments in response to the above-captioned Proposed Rule ("NPRM") on the hospital Outpatient Prospective Payment System ("OPPS"). AKSM is a provider of lithotripsy services to more than 1,200 urologists at hospital and office-based facilities in 20 states. Through its AKSM/Ortho, Inc. subsidiary, AKSM is a vendor of high energy extracorporeal shock wave treatment ("ESWT") supplying more than 550 orthopedic and podiatric physicians at 216 facilities in 20 states. High energy extracorporeal shock wave treatment is a procedure similar to lithotripsy, in which high energy, acoustic pressure waves are used to relieve pain and inflammation in patients with chronic heel pain syndrome (plantar fasciitis) and other musculoskeletal disorders.

For the reasons explained below, we respectfully recommend to the Centers for Medicare and Medicaid Services ("CMS") that—

- **High energy extracorporeal shock wave treatment for chronic plantar fasciitis (code C9721) be re-assigned from New Technology APC 1547 (Level X) either to clinical APC 0055 "Level I Foot Musculoskeletal Procedures" or to clinical APC 0056 "Level II Foot Musculoskeletal Procedures."**

- **New permanent Current Procedural Terminology ("CPT") codes to be included in CPT 2006 to report high energy ESW for treatment of the plantar fascia should be assigned to APC 0055 or APC 0056 and should replace temporary code C9721 beginning January 2006.**

1. Background on High Energy ESWT for Treatment of Plantar Fasciitis

High energy ESWT devices have been approved by the U.S. Food and Drug Administration ("FDA") for the treatment of chronic plantar fasciitis for patients with symptoms of plantar fasciitis for 6 months or more and a history of unsuccessful conservative therapy.[1] High energy ESWT devices use electromagnetic and

[1] Plantar fasciitis is defined in FDA-approved product labeling "as the traction degeneration of the plantar fascial band at its origin on the medial tubercle of the calcaneus." (See, e.g., Summary of Safety and Effectiveness Data for Dornier Epos™ Ultra PMA number P000048 [approved January 15, 2002].)

electrohydraulic technology to generate acoustic shock waves which travel through a water-filled coupling cushion to the therapy head where the shock waves are focused precisely to the target tissue. High energy ESWT devices were adapted from lithotripsy devices which involve substantially similar technology. Lithotripsy devices have been used effectively and safely for over 20 years to treat kidney stones in a less invasive manner than open surgery. The safety and effectiveness of high energy ESWT for treatment of chronic plantar fasciitis has been shown in multi-center, randomized, controlled trials. As a less invasive option than open surgical procedures, physicians may offer high energy ESWT to carefully selected patients with chronic plantar fasciitis that is unresponsive to more conservative therapies (e.g., rest, physical therapy, heel cushions, non-steroidal anti-inflammatory drugs [NSAIDs], corticosteroid injections, orthotics, splinting and casting).

2. Coding for High Energy ESWT

High energy ESWT does not have permanent coding at this time although we understand that a permanent code to report high energy ESW involving the plantar fascia (i.e., for the treatment of chronic plantar fasciitis) has been approved by the American Medical Association's CPT Editorial Panel and will be included in CPT 2006. Currently, there are "C" codes, "G" codes and Category III codes to report various ESWT services, including high energy ESWT of the plantar fascia. Current coding is presented in the Table immediately below—

HCPCS	Description
C9720	High-energy (greater than 0.22mj/mm2) extracorporeal shock wave (esw) treatment for chronic lateral epicondylitis (tennis elbow)
C9721	**High-energy (greater than 0.22mj/mm2) extracorporeal shock wave (esw) treatment for chronic plantar fasciitis**
0019T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy
0020T	Extracorporeal shock wave therapy; involving plantar fascia
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified; high energy
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle
G0279	Extracorporeal shock wave therapy; involving elbow epicondylitis
G0280	Extracorporeal shock wave therapy; involving other than elbow epicondylitis or plantar fasciitis

Under current coding, the appropriate code to report high energy ESWT for treatment of plantar fasciitis in the Medicare hospital outpatient setting is C9721, which was issued effective January 1, 2005. This code has been assigned to APC 1547 "New Technology—Level X ($800-$900)." Code C9720, which is

used to report high energy ESWT for treatment of chronic lateral epicondylitis, is also assigned to APC 1547. The Category III codes (0019T, 0020T, 0101T and 0102T) as well as the "G" codes are not paid under OPPS.

3. **APC Assignment in the Proposed Rule and Recommendation to Re-Assign code C9721 to APC 0055 "Level I Foot Musculoskeletal Procedures" or APC 0056 "Level II Musculoskeletal Procedures"**

In the NPRM, CMS proposes retaining the assignment of code C9721 to APC 1547 with a payment rate of $850. We were not involved with the New Technology APC application for this service and cannot, therefore, comment on any data that may have been provided and which led to CMS's assignment of this procedure to APC 1547. However, we can offer the following information to show that the $850 payment is significantly below the cost involved in performing this procedure.

Facility costs involved in providing high energy ESWT for treatment of chronic plantar fasciitis include the following—

1. Equipment costs. High energy ESWT devices are available at a price of $400,000 each.[2] In addition, annual costs for device upgrading, repairs and preventive maintenance—necessary to ensure continued safe and effective operation of the device—run approximately $30,000-per year per unit. During a procedure, the device is in-use for approximately 21 to 30 minutes for a unilateral procedure and 42 to 60 minutes for a bilateral procedure.

2. Clinical labor. Clinical staff involved with ESWT include ESWT Technologists specifically trained to operate ESWT devices who: (a) set up the machine for the specific indication to be treated, (b) enter patient-specific information to document targeting for the patient record, (c) take directions from the physician regarding device settings during the procedure, (d) document treatment parameters, (e) record targeting images, and (f) clean and disinfect the device and prepare it for the next patient. A nurse also stays with the patient during the entire time the patient is in the treatment room. In total, the ESWT Technologist spends approximately 45 minutes for a unilateral treatment and 75 minutes for a bilateral treatment.

3. Supplies. Supplies include ultrasound coupling gel, syringes, needles, gowns, linens, ultrasound printer paper, disinfectants, and supplies for documentation.

4. Anesthesia. High energy ESWT is a significant procedure that requires regional nerve block. The regional nerve block may be combined with intravenous sedation, monitored anesthesia care, or with local application of anesthetic agent. In some cases, general anesthesia may be required.

5. Procedure room and other overhead expenses. As noted above, the treatment room is in-use for approximately 45 minutes for a unilateral procedure and 75 minutes for a bilateral procedure. In addition, the patient is observed following pre-treatment and post-treatment protocols.

High energy ESWT shares substantially similar technology with extracorporeal shock wave lithotripsy used in the treatment of patients with kidney stones. Equipment costs, clinical labor, supplies and facilities are all substantially similar between high energy ESWT and extracorporeal shock wave

[2] Manufacturers of these devices in the U.S. are Dornier MedTech America, HealthTronics Surgical Services, Medispec and Orthometrix. Price given is list price for Dornier EPOS Ultra.

lithotripsy.[3] Extracorporeal shock wave lithotripsy (code 50590) is assigned to APC 0169 "Lithotripsy" with a 2005 payment rate of $2,542.78 and a proposed 2006 payment rate of $2,552.54. Median costs for code 50590 (and APC 0169) are $2,595.57.[4] Based upon these costs and the substantial overlap with extracorporeal shock wave lithotripsy, high energy ESWT fits economically most closely under APC 0056 "Level II Foot Musculoskeletal Procedures" with median cost of $2,431.58.

Clinically, it would appear that high energy ESWT fits most closely under APC 0055 "Level I Foot Musculoskeletal Procedures" (proposed payment rate of $1,190.97 based upon median costs of $1,211.04). APC 0055 includes codes 28008 "fasciotomy, foot and/or toe," 28060 "fasciectomy, plantar fascia; partial (separate procedure)," 28062 "fasciectomy, plantar fascia; radical (separate procedure)" and 28250 "division of plantar fascia and muscle (eg, Steindler stripping)(separate procedure)." High energy ESWT for treatment of plantar fasciitis shares with these other procedures treatment targeting the plantar fascia. Although high energy ESWT does not involve an open surgical approach, it does require substantial capital equipment not required by these other procedures and requires clinical labor and anesthesia at least as resource intensive as the open procedures.

Therefore, we would recommend that CMS re-assign code C9721 from New Technology APC 1547 to either clinical APC 0055 or 0056. These clinical APCs are clinically and economically more homogeneous with the high energy ESWT procedure for plantar fasciitis than is the New Technology APC to which this procedure is currently assigned.

We understand that CMS typically assigns a procedure to a New Technology APC for a period of 2 years to allow the Agency to collect claims data to inform appropriate APC assignment. In the case of high energy ESWT, we believe the cost data for the substantially similar lithotripsy procedure supported by the information summarized above regarding costs for this specific procedure show that this procedure does not fit under APC 1547. Given the clinical and economic homogeneity with the Foot Musculoskeletal APCs, we believe it is appropriate to re-assign this procedure to one of those clinical APCs beginning in 2006.

We recognize that AKSM submitted a letter to the Advisory Panel on Ambulatory Payment Classification Groups (the "APC Panel") recommending re-assignment from New Technology APC 1547 (with payment at $850) to New Technology APC 1559 (with payment at $2,250).[5] We considered that recommendation to fit the high energy ESWT procedure under a more economically homogeneous APC than under APC 1547. However, upon further consideration, we have determined that one of the clinical APCs for the foot musculoskeletal procedures would fit better both clinically and economically.

4. The New CPT 2006 Code to Report High Energy ESWT Involving Plantar Fascia Should be Assigned to Clinical APC 0055 or 0056

As noted above, we understand that the CPT Editorial Panel has approved a permanent CPT code to report high energy ESWT involving plantar fascia for the treatment of chronic plantar fasciitis. The new code will be included in CPT 2006 and will be effective January 2006. For the reasons summarized above, we recommend that CMS assign the new code to either APC 0055 or APC 0056. In addition, we

[3] Anesthesia for ESWT differs from lithotripsy.
[4] From cost files "hcpcs_medians_1501p.xls" and "median_apc_1501p.xls" dated July 21, 2005 posted by CMS at <http://www.cms.hhs.gov/providers/hopps/2006p/1501p.asp>.
[5] Letter from B. Pennington dated July 18, 2005 included in the APC Panel handout materials at Tab G-18 (page 198).

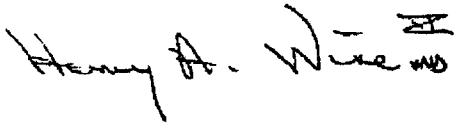
would recommend that CMS discontinue use of temporary code C9721 when the new code becomes effective in January 2006.

* * * *

We appreciate having the opportunity to submit our comments and recommendations to you concerning APC assignment for high energy ESWT for treatment of chronic plantar fasciitis. We hope you will consider our recommendation to reassign this procedure (C9721) from New Technology APC 1547 to either APC 0055 or 0056 for the foot musculoskeletal procedures. We also recommend that you assign the new permanent code for this procedure to either APC 0055 or 0056 and that you discontinue use of the temporary "C" code for reporting this procedure when the new code becomes effective in January 2006.

We would be happy to discuss our comments and recommendations with you. Please contact our reimbursement counsel, Paul Radensky, M.D., J.D., McDermott, Will & Emery, LLP, at 305.347.6557 (or by e-mail at pradensky@mwe.com). Thank you.

Sincerely yours,



Henry A. Wise, II, M.D.
Chairman and Chief Executive Officer
AKSM, Ltd.

Submitter : Ms. Mary Lou Durante **Date:** 09/15/2005

Organization : martin Memorial Wound Medicine Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

Perhaps there was an error in CMS-1501-P regarding the payment rates for wound-healing products such as Apligraf (C1305) and Dermagraft (C9201). It is my belief that these products should continue to be paid in 2006 the same as other such drugs. Both of these biologicals should continue to be paid as a specific drug, at ASP+8%. Under the new (and I believe erroneous) proposal of paying these drugs at rates obtained from claims data the actual reimbursement rates could be a good 30% below actual cost of the product to the facility. This will meant that we will no longer be able to provide this very important product to our patient population. It has been our experience, at our wound center, that both products enhance and expedite healing in diabetic patients who might otherwise take a great deal more time and resources to close. Since our community in Stuart FL is primarily Medicare age we have a very large population of retired patients with diabetes and diabetic ulcers. Treating wounds without being able to use these biologicals when appropriate will have quite a negative impact on our quality of care, our healing rates. We cannot afford to proivde these products at a loss. As you are aware, Medicare cut the reimbursement for the facility to HBO almost in half in January of 2005. Many wound care and HBO facilities like us are struggling with that cut in reimbursement. Coupled with this decrease, we can't, and should not have to pay, approximately 30% of the cost of Dermagraft or Aplilgraf if you stick to the new proposal. I firmly believe that if we are unable to afford to use these products that Medicare costs will actually rise overall. If this proposed ruling on CMS-1501-P for 2006 is not reversed, we will have to stop using them, denying this technology to the patient. We have had wonderful success using thes products on the appropriate patients. Without access to Dermagraft and Apligraf there will likely be more MRSA infections acquired when wounds don't heal as quickly, and more lower extremity amputations. Please correct this error as soon as possible and ensure that Dermagraft and Apligraft are reimbursed as a specific covered drug, at ASP+8%.

Submitter : **Mr. Ross Thompson** **Date: 09/15/2005**

Organization : **Mr. Ross Thompson**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

I am writing with concerns related to the July 25, 2005, Federal Register notice, where CMS has proposed to pay for outpatient drugs and biologicals at 106 percent of the manufacturer's average sales price (ASP). This proposed payment will create substantial hardship to outpatient / retail pharmacies and ultimately degrade the quality of care our profession provides to our patients.

I have reviewed multiple reports that show labor costs far exceed the 6% margin that is being proposed. These operations require margins of 12% to 20% to cover acquisition and operating costs and provide an adequate profit to maintain the business. Lowering reimbursement will result in inappropriate consolidation of services that will diminish the quality of patient care pharmacists can provide. Instead of a face-to-face interaction being possible, patients will be forced to acquire drug from mail-order operations who offer a fraction of the pharmacy services that many patient need.

Further, reimbursing solely on a percentage margin of supply cost will create scenarios where the pharmacy is penalized for optimizing utilization and resource consumption through programs such as generic substitution. In order to cover our operating costs, we will be tempted to dispense higher cost drug simply to generate higher revenue to insure we can stay in business. Instead of what many of us do each day as we work with patients to minimize the cost of therapy and / or minimize the number of prescriptions within that patient's drug therapy. There should be dispensing and / or counselling fees associated with pharmacist's cognitive services being provided to patients every day across the country.

I would like to voice my support of the Association of Community Cancer Centers (ACCC) proposal that CMS consider an allowance of 8% to cover pharmacy handling and overhead expenses for all drugs reimbursed under the hospital OPPS, in addition to ASP + 6% to cover the drug acquisition cost.

I am hopeful that any decision that is made will be evaluated over the first several months to determine the impact on quality of service being provided and the overall costs of drug therapy which I suspect will rise due to the factors I've outlined.

Thanks for your consideration in this matter.

Respectfully,

Ross W. Thompson, M.S., R.Ph.

Submitter : **Dr. Joseph Roberson, Jr.**

Date: 09/15/2005

Organization : **California Ear Institute**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-456-Attach-1.DOC

September 15, 2005

Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. box 8010
Baltimore, MD 21244-8018

Re: Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; CMS-1501-P; Proposed Recalibration of AOC Weights for CY 2006

Dear Dr. McClellan:

On behalf of California Ear Institute, we are pleased to submit the following comments on the proposed rule CMS-1501-P. We are concerned to see the proposed 14% decrease in payment for cochlear implantation (APC 0259) in 2006. The proposed payment under the outpatient prospective payment system (OPPS) is less than our hospital's cost to acquire the cochlear implant device and provide associated surgical services. We are concerned that payment for cochlear implantation has not been accurately calculated because the data analyzed by CMS is not representative of the costs of the device and procedure. We would request that CMS substitute accurate external device cost data as determined by The Lewin Group study and recalculate the relative weight of APC 0259.

California Ear Institute has been providing cochlear implants to patients since 1992. Since 1997 our clinic has implanted over 300 patients with 52 of those patients implanted in 2004. Our center has already reached 31 implants in 2005. As cochlear implant technology expands to a larger patient population, the demand for surgeries will increase.

A limited number of centers, roughly 350 nationwide, provide cochlear implantation. Due to a shortage of qualified clinicians, there are capacity constraints on increasing the number of centers. The proposed reduction in the level of reimbursement would reduce the number of centers offering cochlear implantation thus making access to implants and follow-up care even more difficult for Medicare beneficiaries as well as others. Additionally some centers may be forced to discontinue offering cochlear implantation as the level of reimbursement decreases. This would only further decrease access of Medicare beneficiaries to this procedure.

Those Medicare beneficiaries fortunate enough to receive this technology receive extraordinary benefits allowing them to lead lives of increased independence and remain self-sufficient. The cost-effectiveness of cochlear implantation has been well documented by a large body of evidence-based literature and accepted by the medical profession and by insurers.

In conclusion, we request that CMS set the 2006 OPPS payment no lower than 100% of the 2005 payment rate plus the inflation and other update factors applied to all APC's.

California Ear Institute acknowledges CMS's responsiveness in working with cochlear implant providers and manufacturers to date in ensuring adequacy of Medicare payment rates despite problems with the hospital outpatient payment system methodology that makes it difficult for CMS to accurately track actual device costs. We appreciates the agency's recognition of the potential impact of payment rates on access to care and hopes that you will consider carefully the comments and recommendation that we have submitted. If you require additional information, please do no hesitate to contact Monica Hellner at 650-494-1000.

Sincerely,

Joseph B. Roberson, Jr., M.D.
CEO

Submitter : **Ms. Mary Lou Durante, RN Director** **Date: 09/15/2005**

Organization : **Martin Memorial Wound Medicine Center**

Category : **Nurse**

Issue Areas/Comments

GENERAL

GENERAL

Perhaps there was in error in CMS-1501-P regarding the payment rates for wound healing products such as Apligraf (C1305) and Dermagraft (C9201. It is my belief that these products should continue to be paid in 2006 the same as other such drugs, as a specific drug at the ASP+8%.
Under the new (and I belive erroneous) proposal of paying these drugs at rates obtained from claims data the actual reimbursement rates from Medicare will be about 30% less than the cost of the product. We cannot absorb that! Nor should we have to. The error should be corrected immediately. If this is not done, we will no longer be able to provide this very important product to our patients. Since we live in South Florida we have a very large population of Medicare patients who are diabetic and have diabetic ulcers. The use of these two products has been very important to us in appropriate cases to obtain wound healing where other methods have failed. If we cannot provide Dermagraft of Apligraf to our patients, there will likely be more diabetic ulcers that are non-healed and become infected with MRSA, and perhaps even more lower extremity amputations. This will cost Medicare more in the long run. Not being able to use these products will cause a definite decrease in quality care and healing rates. If the current propoal on CMS-1501-P is not changed we will be unable to provide this treatment option to our patients in our wound center. Please correct this error as soon as possible and ensure that Dermagraft and Apligraf are reimbursed as a specific covered drug, at ASP+8%.

Submitter : **Ms. Barbara Marone** **Date: 09/15/2005**

Organization : **American College of Emergency Physicians**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : **Ms. Ann Langan** **Date: 09/15/2005**

Organization : **St. Cloud Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

see attachment on Partial Hospitalization.

CMS-1501-P-459-Attach-1.DOC

September 15, 2005

Mark B. McCellan, M.D., Ph. D.
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W. Room 445-G
Washington, DC 20201

Re: CMS-1501-P Medicare Program; Proposed changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Rates; Proposed Rule (vol. 70 , No. 141 *Federal Register*), July 25, 2005.

Dear Dr. McClellan:

I am writing in response to the above-referenced proposed rule. In this proposed rule, the Centers for Medicare and Medicaid Services (CMS) has asked for comments on the various areas of this proposed rule. The following comments are on the section of proposed payment for Partial Hospitalization.

Partial Hospitalization:
We are writing on the proposed 15% reduction in the partial hospitalization per diem payment as described on pages 42692 through 42694.

We are a hospital based partial hospitalization program (PHP) located in central Minnesota providing adolescent, adult and child PHPservices. We have recently expanded our partial hospitalization program due to the need that is present in the surrounding area. We have experienced good patient outcomes with our partial hospitalization program and have operated this program in a cost efficient manner. Our average cost per day for our PHP is approximately $300 for Medicare patients. Our inpatient psychiatric unit has an average cost per day of $1,115 for Medicare patients. We have made a significant commitment to providing a partial hospitalization program to this area since we have had success meeting the patient needs for care yet provide this care in a lower cost outpatient setting than in an inpatient setting. This program is good for the patient and good for Medicare. Therefore, we are concerned to read that CMS is proposing a 15% reduction in the PHP per diem from $289 to $245.65.

We are concerned about the Medicare cost report data that CMS is using to attempt to establish the CY 2006 per diem. CMS has described the difficulties they are having with obtaining consistent accurate cost report data from the CMHCs. In addition, we believe the hospital based PHP cost report data is generating a low per diem because they are sharing their administrative staff between their inpatient psychiatric unit and their partial hospitalization program. The CMHCs can not share their administrative staff which results in a higher per diem.

We believe CMS should delay the 15% reduction and work with the CMHCs to improve their cost reporting data. Without consistent, accurate cost report data, we do not believe CMS has proven that a 15% reduction would ensure an adequate payment amount and continue to ensure access to the partial hospitalization benefit for the Medicare beneficiaries. We believe CMS should be rewarding the cost effective alternatives to inpatient care rather than making these alternatives like partial hospitalization less attractive by decreasing the Medicare reimbursement. If the Medicare per diem is reduced, many providers may choose to reduce their partial hospitalization programs to limit their losses.

One reason the per diem cost for the CMHCs varies so much may due to the fact some of the CMHCs are new to the partial hospitalization program. If CMS could survey their intermediaries

for the diem costs for the CMHCs from their most recently filed cost report, this may provide the best per diem cost data for the CMHCs for CY 2007 per diem. By using the most recently filed Medicare cost reports for the CMHCs, CMS would obtain a cost-to-charge ratio for each CMHC that would be appicable to the same time period of the partial hospitalization charges with condition code 41 for each CMHC.

We do not believe CMS will have time to conduct such a survey in time to establish the CY 2006 per diem therefore, we again ask CMS to delay the 15% reduction until consistent, accurate cost report data can be obtained from the CMHCs.

Thank you for consideration of our comments on this proposed rule. If you have any questions about these comments, please contact me at (320) 251-2700, extension 54697.

Sincerely,

Ann Langan
Reimbursement Accountant

Submitter : **Mr. Philip Johnson** **Date: 09/15/2005**

Organization : **Hematology Oncology Pharmacy Association (HOPA)**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

Comment on Proposed Outpatient Prospective Payment System (OPPS) Rates for 2006. See Attachment.

CMS-1501-P-460-Attach-1.DOC

Hematology/Oncology Pharmacy Association
Philip E Johnson MS RPh
HOPA Treasurer / Board Liaison to Legislative Affairs Committee
Director of Pharmacy, H Lee Moffitt Cancer Center
12902 Magnolia Dr., Tampa, FL 33612

Mark B. McClellan MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

September 15, 2005

Re: Proposed Outpatient Prospective Payment System (OPPS) Rates for 2006

Dear Dr. McClellan:

HOPA is a professional organization comprised of approximately 600 pharmacist clinicians, educators and researchers who specialize in hematology and /or oncology. HOPA empowers its members to provide optimal cancer care through educational activities, provide research and information that promotes safe and cost-effective use of cancer-related treatments, promote and support excellence in clinical practice, act as patient and practice advocate to policy makers on behalf of oncology pharmacy professionals, partner with professional organizations that promote safe and effective cancer care, and increase public awareness of the value of oncology pharmacists. Our members practice at more than 250 healthcare institutions, including most of the NCI Designated and Comprehensive cancer centers.

HOPA respectfully but urgently requests that CMS consider:

1) Increasing the OPPS payment rates for 2006 to cover true handling costs and dampen the impact of the ASP + 6% + 2% formula that has been proposed.

2) Applying payment rates to all drugs, not just separately paid drugs.

3) Reconsider the process currently proposed to establish C-codes for drug handling in 2008, incorporating input from the pharmacy organizations such as HOPA and ASHP during 2006, with evaluation during 2007, and implementation in 2008.

4) Consider the emerging variables, including unfunded regulatory mandates that are driving the complexity and cost of healthcare to ever-higher levels when developing future OPPS budgets and reimbursement strategies.

Background

The CMS proposal to reimburse pharmacy-handling costs at 2 percent of the average sales price (ASP) of separately paid drugs is inadequate to compensate for the costs of storing, preparing, transporting, and disposing cancer drugs and biologicals. In addition, the essential clinical services provided by cancer centers exceed the basic order processing and dose checking itemized in the initial CMS proposal that describes "handling costs". Further, the Medicare Payment Advisory Commission (MedPAC) report, prepared at the direction of Congress to help CMS in setting these rates, found that handling costs, when fully burdened in a manner consistent with the Medicare Cost Reports accounted for 26 to 28 percent of pharmacy departments' direct costs. In a survey of HOPA institutions, compiled September 13, 2005, we found that the average respondent documented handling costs that are 30.75% of pharmacy department's direct costs. Clearly the MedPAC results are reasonably accurate based on a comparison with HOPA data.

HOPA believes that the CMS proposal also fails to recognize that every drug, including those that are not paid separately, has significant handling costs, for example; a) all drugs, regardless of acquisition cost require essentially the same inventory processing costs, b) all controlled substances require additional record keeping, c) all compounded injectable drugs require an aseptic preparation area, diluents, and other preparation paraphernalia. Some drugs account for additional costs related to supplies and labor, such as: a) paclitaxel requires special tubing and handling, b) cyclophosphamide is difficult to dissolve and requires up to 5 minutes per vial to go into solution, c) high dose therapy such as methotrexate, busulfan or thiotepa require as many as 80 vials per dose, d) many therapies require checking lab values and discussion between a pharmacist and physician before the dose can be prepared, e) drugs given via intrathecal route (IT) require preparation in a sterile field, using cold sterilization that adds 10 – 15 minutes and supply costs to the procedure, and f) chemotherapy drugs such as carboplatin and rituximab have significant infusion related toxicities that require close monitoring by both pharmacy and nursing that adds time and cost to the drug administration process.

For future budgets, CMS should consider that drug related costs continue to escalate because of new variables that extend beyond direct or acquisition costs or current handling costs, and therefore CMS should request the Congress to allocate additional funds for the Medicare OPPA program. These new variables include; a) rapid development and adoption of new genetic and biologic based drug therapy technology (e.g. targeted agents such as the anti-VEGF agent bevacizumab (Avastin-®), b) implementation of new rules such as USP797 and NIOSH that will increase labor and supply costs, c) increased labor costs required for national safety initiatives, d) labor and software costs required to implement medication reconciliation strategies, and e) the expanding and essential role of pharmacy staff in the safety and efficacy of drug therapy. For example, HOPA estimates that the

cost of implementing USP797 standards will add a one time renovation cost of $300,000 to $1 million to the pharmacy, with an additional operating cost estimated to be 2% for supplies and 1% for labor, thus increasing pharmacy "handling costs" by 3%, and projecting the HOPA average indirect costs to be 33.75% of direct costs.

Impact of ASP +8%

Based on models using all HCPCS coded cancer and supportive care drugs, we determined that the ASP +8% model will result in an aggregate drug reimbursement loss for our member hospitals, with some drugs facing significant payment reductions such that they will be financial losers. We calculated that into a percent gain or loss when compared to 2005 HOPPS reimbursement and determined that the current proposal will result in a 5 – 9% loss. Dampening that impact by paying the greater of ASP +8%, or a percent of the 2005 APC reimbursement, allows CMS to gain experience with the ASP model in the HOPPS setting while modulating the impact on providers. In our analysis of the "ASP+8 or _X_% of APC" model, we found that when the 2005 APC is paid at 85%, the result is a financial loss of from 4 – 6%; for 90% the loss is 2 – 4%, and for 95% the impact is neutral.

Recommendations to CMS

HOPA realizes that the goal of CMS is to be budget neutral, and to look for a better process to be initiated in 2008 based on HCPCS codes linked to each drug. HOPA also understands that CMS, when faced with proposals that will cause significant hardship to providers, has historically found ways to dampen the impact. Based on that, HOPA recommends the following.

For 2006 OPPS payment:

1) For each drug, pay the GREATER of ASP +8%, or 95% of the 2005 APC payment. This formula will give results that are as close to 2005 reimbursement rates as possible, and therefore budget neutral.

2) We recommend that CMS apply this payment to all drugs administered in the outpatient department, regardless of whether they are separately paid. Several supportive care drugs that were "bundled" prior to 2005, were then "unbundled" in 2005, and their status is unknown for 2006. Since all drugs have an acquisition cost and involve some level of handling, we urge CMS to find a mechanism to pay a handling cost for all drugs, regardless of whether they are separately payable or packaged. Some of our least expensive drugs (e.g. 5-flourouracil and etoposide) have high toxicity and require close monitoring. All drugs must be "handled" during the preparation and dispensing process, including special precautions that

must be taken with hazardous drugs requiring utilization of additional supplies and staff / labor.

2008 Handling Codes

HOPA is concerned with the CMS proposal to create only three payment classes for handling costs. MedPAC recommended that CMS group drugs into seven categories based on the varying levels of resources needed to prepare drugs for administration. Three categories may not be enough to reflect the significant cost differences that range between dispensing simple prepackaged drugs, and drugs that require extensive compounding, complex storage and extensive clinical management. Preparations listed in category 2, for example, could be as simple as a single drug drawn from a vial with a syringe taking less than a minute, or as complex as adding 12 or more solutions in a complex admixture that takes 30 minutes to prepare and utilizes significant supplies. HOPA asks that CMS reconsider its proposal to implement the newly proposed drug handling C-codes in 2006 and instead work with pharmacy organizations such as HOPA and ASHP to more fully review and develop drug handling categories that are more appropriate.

Thank you for the opportunity to present these issues on behalf of HOPA.

Respectfully Submitted of Behalf of HOPA,

Philip E Johnson MS RPh
HOPA Treasurer / Board Liaison to Legislative Affairs Committee
Director of Pharmacy, H Lee Moffitt Cancer Center
12902 Magnolia Dr., Tampa, FL 33612
813-979-3967
johnsonp@moffitt.usf.edu

Submitter :

Date: 09/15/2005

Organization :

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

September 14, 2005

Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1501-P

To whom it may concern,

I am writing to you regarding the CMS proposal to reduce the payment for cochlear implantation to $21,739 in 2006 from $25,507 in 2005. I am requesting that CMS set the 2006 Outpatient Prospective Payment System payment at no lower than the 100% of the 2005 payment rate plus the inflation and other update factors applied to all APC's. This reduction is a loss of 14% for the device and the procedure. The reduction in reimbursement may have a severe impact on the Medicare beneficiary accesst o cochlear implantation.

Cochler Implants have allowed patients with significant degrees of hearing loss to return to a hearing world. Many of the cochlear implant recipients are even able to converse on the telephone with the newer programming strategies. Medicare patients who are cochlear implant recipients return to independence and have the ability to remain self-sufficient. These patients are more positive after implantation and this translates directly to an improvement in "quality of life" for the Medicare cochlear implant recipient. The medical profession and insurers realize the "cost effectiveness" of cochlear implants has been well-documented. The "cost effectiveness" of cochlear implantation is analogous to a "cardiac pacemaker" or "joint replacement." These medical procedures allow the Medicare beneficiary to return to "quality of life" that was previously enjoyed.

There are about 350 centers nationwide providing cochlear implantation. The proposed level of reimbursement would reduce the numer of centers offering cochlear implantation and hamper the access for implants and follow-up care for Medicare beneficiaries. At present there are Medicare beneficiaries who only have Medicare insurance. These patients do not have the luxury of a secondary insurance to cover the 20% patient responsibility. These patients because of the "20% balance" may not be allowed access to cochlear implantation. If this reduction occurs, the Mediare beneficiary' s out of pocket expenses become greater.

Once again, I urge you not to reduce the OPPS payment for cochlear implantation for 2006. Reduction of this reimbursement for the Medicare beneficiary may have a negative impact on economic growth of centers performing implants, qualified audiologists entering the profession and most importantly the quality of life of the Medicare beneficiary.

Medicare has just revised the cochlear implantation guidelines to include medicare beneficiaries with a greater amount of residual hearing (Medline Matters Number: MM3796). CMS is aware of the benefits of cochlear implantation and has expanded coverage to even include patients who are in clinical trials and studies with even better performance on ope-set speech recognition tests.

In summary, I would like to thank you for CMS's support of cochlear implantation and their responsiveness in working with providers and manufacturers in ensuring adequacy of Medicare payment rates despite hopsital problems with the hospital outpatient payment system that makes it difficult for CMS to accurately track acutal device costs. Thank you in advance for taking the time to read my comments on behalf of the Medicare beneficiary.

Sincerely,

Lisa C. Guidone, MS, Audiologist

Submitter : **Ms. Gail Blakely** **Date: 09/15/2005**

Organization : **South Bay Mental Health, Inc.**

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-1501-P-462-Attach-1.DOC

CMS-1501-P-462-Attach-2.DOC

CMS-1501-P-462-Attach-3.DOC

September 15, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS-CMS-1501-P

South Bay Mental Health, Inc. is a freestanding Community Mental Health Center in Massachusetts. We have been providing Partial Hospitalization services since 1995. Our initial response regarding CMS-1501-P and a 15% rate reduction for CY2006 was overwhelming. The very existence of this service will be threatened for the future if our facility must absorb this amount of revenue reduction.

It is very difficult to convince boards and administrative authorities to continue programs year after year on a break-even basis at best. A $40/day reduction will be an impossible task. CMS must reconsider this position or many facilities will have to take drastic action, which will likely cause many programs to close or to be severely limited.

As a member of the Association of Ambulatory Behavioral Healthcare, our organization stands firmly behind the comments they submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1501-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of $289.00. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, transportation, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas. A daily per diem of $241.57 cannot be justified with these expenses.

2. CMS identified the Median cost of group therapy at $82.31. Our program offers 5 services per day at a minimum. This summarizes to a median cost of $329.24. A per diem of $241.57 cannot be justified with these expenses.

3. Many of our patients have both Medicaid and Medicare. Medicaid cuts are strongly threatened here in Massachusetts. If the 20% co-pay is unavailable, the per diem would shrink even further and eliminate any consideration for these programs to exist. This would virtually reduce the per diem to $193.26 ($241.57 x .80). A daily per diem of $241.57 cannot be justified with this situation.

4. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally two years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two year periods.

5. Based on the above issues, South Bay Mental Health, Inc. asks that CMS leave the per diem unchanged from the CY 2005 rate of $281.33. The proposed rate is not sufficient to cover the costs needed for our intensive program.

If rates are slashed and our program cannot continue, the inpatient demands will grow substantially as there are no other alternative services for this needy population in our community. Our PHP program has had over one hundred admissions so far in CY 2005, and every one would be a high risk candidate for inpatient admission without the PHP availability.

Thank you for your consideration of our comments. We look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

Sincerely,

Gail Blakely, MS
Director of Day Services

Cc: Peter Scanlon, CEO

September 15, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS-CMS-1501-P

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Thank you for your consideration of our comments. We look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

Sincerely,

Gail Blakely, MS
Director of Day Services

Cc: Peter Scanlon, CEO

Submitter : Mr. Michael Breen

Date: 09/15/2005

Organization : St. John Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERIVICES
OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

Submitter : Mr. Casey Crimmins **Date: 09/15/2005**

Organization : University of Michigan Hospital

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-464-Attach-1.DOC

University of Michigan
Hospitals and
Health Centers

Accounting and Reimbursement Services
2500 Green Rd. Suite 100
Ann Arbor, Michigan 48105-1500
734-647-3321
734-647-0026 Fax

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1501–P.
7500 Security Boulevard
Baltimore, MD 21244-1850

September 14, 2005

Re: CMS–1501–P.
Hospital Outpatient Prospective Payment System,
Calendar Year 2006 Proposed Rule
Federal Register Dated July 25, 2005

The University of Michigan Health System (UMHS) appreciates the opportunity to comment on the proposed rule for 2006 Hospital Outpatient Prospective Payment System (OPPS)

Indirect Medical Education Adjustment

An Indirect Medical Education (IME) adjustment is needed to account for the higher costs incurred by major teaching hospitals. The financial performance of major teaching hospitals under OPPS has lagged far below other hospitals, as borne out by CMS' own impact analysis. At the inception of OPPS major teaching hospitals had lower payment-to-cost ratios than other hospitals and the gap has widened each year. From FY 2000 to FY 2006, based on the annual CMS impact analysis, the cumulative increase in major teaching hospital payment rates has been 18%, compared to 32% for minor teaching hospitals and 30% for non-teaching hospitals.

In direct response to a comment in the Interim Final Rule Published November 13, 2000 (65 FR 67818) addressing the OPPS impact on Teaching Hospitals, CMS stated:

"We will perform further comprehensive analyses of cost and payment differences between different classes of hospitals as soon as there is a sufficient amount of claims data submitted under the prospective payment systems. We will use data from the initial years of the prospective payment system to conduct regression and simulation analyses ... These analyses will be used to consider and possibly propose adjustments in the system, particularly beginning in 2004 when the transitional corridor provision expires."

Transitional corridor payments expired on December 31, 2003 for most hospitals, and CMS now has several years of claims data. However, we are aware of no CMS analysis to address the cost and payment differences associated with teaching status since the inception of OPPS.

In contrast, CMS performed an extensive analysis this year to assess whether rural hospitals have higher costs than urban hospitals, for the purpose of determining whether an adjustment for this class of hospitals is warranted. We agree that rural hospitals face special challenges that warrant

consideration in a prospective payment system. Major teaching hospitals face challenges in a PPS environment that are no less daunting and deserve the same consideration.

With the adoption of an IME in the inpatient rehabilitation facility PPS this fall, every Medicare PPS except OPPS has an IME adjustment. We believe that the same factors that support an IME adjustment in the inpatient systems exist in the hospital outpatient environment as well:

- Significant and demonstrable cost differences for the major teaching hospital class.
- More complex patient populations whose complexity is not adequately measured by the payment groups.
- Inherent inefficiencies associated with graduate medical education, as residents are spending a great deal of their training time in outpatient and ancillary areas.

We recall that when CMS analyzed the impact of teaching programs prior to the inception of OPPS, the findings were less persuasive than they have been in the inpatient settings. One issue may have been that CMS attempted to apply a resident-to-bed ratio to outpatient services. There should be more effective ways to relate the size of a hospital's teaching program to the volume of outpatient services provided, such as an outpatient equivalent-discharge statistic. We recommend that CMS evaluate different ways to construct a teaching variable that is relevant to the outpatient setting and produces a statistically valid adjustment.

We strongly urge CMS to address the inequities faced by major teaching hospitals, and develop an IME adjustment as soon as possible.

Conversion Factor ***(Federal Register page 42694)***

The proposed OPPS update factor is 3.2 percent, based on the estimated market basket increase made in the May 2005 IPPS proposed rule. However, the hospital market basket increase for FY 2006 published in the IPPS final rule is 3.7 percent update,

UMHS requests CMS to revise the market basket update included in the final OPPS rule to include a 3.7 percent market basket update, consistent with the inpatient final rule.

Wage Index ***(Federal Register pages 42695 – 42698)***

CMS believes, and we concur, that using the IPPS wage index as the source of an adjustment factor for OPPS is reasonable and logical, given the inseparable status of the hospital outpatient services within the hospital overall.

The IPPS final rule (70 FR 47392) Friday, August 12, 2005 summarizes an extensive analysis related to labor related share component of payments. Based on this research, CMS implemented a reduction to the labor-related share to 69.7% of the total.

Since CMS continues to rely on IPPS for OPPS wage index purposes, we believe CMS should also rely on the IPPS for the OPPS labor-related share. It is our understanding that the data used to set the labor-related weights for IPPS purposes do not separate inpatient-only activity, just as the area wage data does not separate inpatient from outpatient. Therefore, it is logical that the IPPS labor-related weights would be as applicable to hospital outpatient services as are the wage index data.

UMHS requests CMS to revise the OPPS labor related share to 69.7 percent consistent with the inpatient final rule.

Drug Handling Charges ***(Federal Register pages 42728 – 42731)***

CMS intends to reimburse for pharmacy overhead and handling expenses by adding on 2% of Average Sales Price for FY2006, and collecting cost data by establishing three distinct HCPCS C-codes.

We fully support a drug handling adjustment to the acquisition cost-based payment, but the distinct C-codes would be extremely complex and burdensome for hospitals to implement.

- Hospitals would have to establish handling charges for separately payable drugs under Medicare while the drug handling charges for packaged drugs would remain incorporated within the overall charge for the drug.

- For each separately payable drug, hospitals will need to assign the handling charge to one of the CMS' proposed new drug handling C-codes. These codes are only recognized by and acceptable to Medicare, but not other payers. Other payers may follow suit, however, there will be a time lag and any future changes will have the same issue. Hospitals will therefore have to modify their billing systems to separate out the drug handling from the drug charge for Medicare claims but bill them as a single line item for other payers.

- There is confusion regarding how the handling C-codes would apply when a hospital pharmacy mixes multiple doses of a drug for a patient.

- Many hospitals use the same charge master for inpatient and outpatient services. If the handling charge must be separated out of the drug charge for the outpatient setting, there are questions regarding how CMS will expect providers to report drug charges in the inpatient setting versus the outpatient setting.

UMHS opposes this expansion of the drug handling C-coding proposal to packaged drugs. This would exponentially increase the coding and administrative burden due to the sheer number of drugs that would require special charging practices for Medicare purposes. Instead CMS should consider a survey to estimate the average cost of drug handling, taking into consideration that multiple formulations may force CMS to stratify individual drugs into assumed categories.

Drug Administration ***(Federal Register pages 42737 – 42739)***

CMS is proposing to crosswalk current drug administration CPT codes to new CPT codes expected to be active in 2006. These codes may correspond to the G-codes currently used in the physician office setting.

The hospital setting is much larger and more complex than the physician setting. The current physician codes separate out initial intravenous infusion from subsequent infusion and Hydration infusion from Therapeutic/Diagnostic infusion. These codes may not translate well or be very burdensome to implement. For example, if a patient starts in the Emergency room with initial hydration therapy and receives an initial diagnostic therapy in another department we will have a very difficult time coding according to current physician rules which only allow one initial code

per visit. Since there have been significant changes in this area over the past years it would be beneficial to have some consistency and have some time to evaluate the proposed changes prior to implementation.

UMHS recommends that the current coding remain in place until the new CPT codes and crosswalk are established and hospitals have a chance to review and comment on the specifics of the proposed changes.

Evaluation and Management Services ***(Federal Register page 42740)***

CMS is developing and testing new evaluation and management codes and guidelines and will give a minimum notice of between 6 and 12 months prior to implementation. Adopting a new scheme for assigned levels/codes will be an enormous undertaking for a large, complex medical center such as UMHS. In our last fiscal year, we performed over 1.6 million outpatient visits in over 100 locations, and the majority of these sites will be affected by the new guidelines.

UMHS recommends that CMS provide at least 12 months prior to implementation to prepare for the changes and train staff. Also, for a change of this magnitude, UMHS would like CMS to ensure that there is adequate opportunity to review and comment on the new guidelines before they are finalized.

Blood and Blood Products (Federal Register pages 42740 – 42742)

CMS proposes to establish payment rates for blood and blood products based on their 2004 claims data. CMS is proposing to limit the decrease in current medians to 10 percent.

The payment rate for leukocyte-reduced red blood cells (APC 0954), the most commonly transfused blood product, and rates for certain other blood and blood product APCs will continue to decline under this methodology. According to data from the American Association of Blood Banks, the proposed rate for several of these blood products is significantly below hospitals' actual acquisition cost for blood. This problem will continue to increase with the introduction of additional blood safety measures making the proposed Medicare payment rate even more inadequate.

To ensure continued beneficiary access to all blood and blood products, the UMHS recommends that CMS set 2006 rates at *the greater of*: (1) the simulated medians calculated using the 2004 claims data; or (2) the 2005 APC payment medians for these products.

Observation Services ***(Federal Register pages 42742 – 42745)***

CMS proposes to discontinue current HCPCS codes used for observation and replace them with two new HCPCS codes. (GXXXX _Hospital Observation per hour and GYYYY Direct admission for observation care.) CMS also proposes to shift determination of whether or not observation services are separately payable from the hospital billing department to the OPPS claims processing logic.

UMHS fully supports the shift of determining observation services as separately payable under APC 0339 from the hospital billing department to the OPPS claims processing logic.

Inpatient Services. ***(Federal Register pages 42745 – 42746)***

CMS proposes to remove 25 procedures from the inpatient list and assign 23 of these to APC's while the 2 Anesthesia CPT codes will be package into the procedures billed.

UMHS supports the reduction of procedures on the Inpatient Only Procedure List. However, we would prefer the elimination of the Inpatient Only Procedure List. For one, we believe the determination of care and its setting should reside with the physician. Second, until CMS completes its annual deliberations about which procedures to remove from the List, hospitals that are performing these procedures on an outpatient basis are providing these covered services for free.

Assuming the list is not eliminated in the final rule, please review the following for appropriateness in an outpatient setting.

37182	C	Insert hepatic shunt (tips)
45563	C	Exploration/repair of rectum
61624	C	Occlusion/embolization cath

Multiple Diagnostic Imaging Procedures ***(Federal Register pages 42748 - 42751)***

CMS is proposing to pay 100 percent for the diagnostic imaging procedure with the highest APC payment rate, and pay only 50-percent for each additional imaging procedure when all the procedures are performed during a single patient encounter and all are within an identified "family" of procedures that are commonly billed on the same day. The CMS identified 11 "families" of imaging procedures by imaging modality and by contiguous body area. In developing this policy, the CMS did not examine hospital cost data but relied on Medicare physician fee schedule practice expense data for determining the discount level.

UMHS opposes this policy and believes further study should be done before implementation. It is our belief that the current rates already accurately reflect any presumed cost savings of performing multiple procedures. No evidence has been presented to justify the reduction in payment or to suggest that the 50 percent discount represents the appropriate level of efficiencies obtained by hospitals, if they even exist.

****

Once again UMHS would like to thank you for the opportunity to comment on the OPPS proposed rule. If you have any questions or would like some clarifications please contact me at (734) 647-3322

Sincerely,

Casey Crimmins, Manager
Accounting and Reimbursement Services
University of Michigan Hospitals and Health Centers

Submitter : Mr. Gary Delhougne **Date:** 09/15/2005

Organization : Tyco Healthcare / Valleylab

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-465-Attach-1.DOC

tyco / Healthcare / Valleylab

September 15, 2005

Submitted Electronically to: www.cms.hhs.gov/regulations/ecomments
Submitted via Federal Express

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington DC 20201

Re: CMS-1501-P
Medicare Program: Hospital Outpatient Prospective Payment System and Calendar year 2006 Payment Rates; Proposed Rule

Dear Dr. McClellan:

Valleylab, a division of Tyco Healthcare Group LP, is submitting these comments in response to the August 25, 2005 proposed rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates. Valleylab is a developer, manufacturer, marketer, and distributor of devices used for radiofrequency ablation of tumors. Valleylab is submitting comments specific to Section II "**APC Relative Weights**".

Comment

Valleylab respectfully requests that CMS re-evaluate the methodology used for determining the Median Cost for CPT 76362. Based on an analysis by The Moran Company, an anomaly was identified associated with the single claims calculation for CPT 76362. Valleylab requests that CMS consider The Moran Company's findings and assign CPT 76362 to a New Technology APC (1507) in 2006 for further data analysis. We are requesting CPT 76362 be moved to a New Technology APC because CT guidance for tissue ablation is essential to the therapeutic intervention of radiofrequency ablation of tumors and lesions.

INTRODUCTION TO CT GUIDANCE AND RADIOFREQUENCY ABLATION

CT guidance is essential to the successful ablation of lesions or tumors. CT scans are used by the physician to locate and then guide the ablation device into the tumor or lesion. Radiofrequency ablation involves the laparoscopic, percutaneous, or intraoperative insertion of an electrode into a lesion or tumor under imaging guidance. Radiofrequency energy is emitted through the electrode to generate heat, leading to coagulative necrosis of the lesion or tumor.

CURRENT STATUS OF CPT 76362

Computerized tomography guidance for tissue ablation was introduced as a CPT code in 2002 and revised in 2004. Currently CPT 76362 is assigned to APC 332, Computerized Axial Tomography and Computerized Angiography without Contrast. The recently published Outpatient Prospective Payment System (OPPS) Proposed Rule of August 25, 2005 retains CPT 76362 in APC 332 with a proposed payment rate of $194. The Median Cost for 9 single claims associated with CPT 76362 published in CMS's Median Cost File was $371. Additional analysis conducted by The Moran Company showed that an incremental 202 claims with a Median Cost of $580 can and should be considered in the calculation and review of the APC assignment for CPT 76362.

DATA SUPPORTING COMMENT

We engaged The Moran Company (TMC) to replicate the methodology used by CMS to distinguish single and multiple procedures. In their analysis, TMC identified a previously unknown "exception" to the methodology described in the July 25, 2005 NPRM. Specifically, the TMC analysis found that, when a claim had both CPT 76362 (status indicator "S") and another major procedure, that claim was not being considered as a multiple claim but instead was counted as a single claim for the other CPT.

By definition, a claim can only be regarded as originally single if it contains only one "major" procedure. However, some "originally single claims", identified by CMS as an original single (PUF_TYPE ='SMAJ') contain CPT codes 47370, 47382, 50542, and 20982 and CPT 76362. Based on our simulations, we conclude that CPT code 76362 is not being treated as a "major" procedure for the purpose of creating single and multiple claims. TMC has not been able to determine, for the codes with a "major" procedure and CPT 76362 on a single claim, whether CMS is packaging the cost for this procedure into the adjusted cost finding for the major procedure.

The TMC review of the current NPRM and historical related rulemakings did not find a specific reference to the decision to treat this code different from other "S" status indicator procedures. This code is not listed on the current bypass list. As a result, TMC could not determine whether this "exception" was intended or an anomaly.

TMC simulated the effects of removing this exception. Their analysis revealed that there will be a reduction in single claims for other major procedures billed with CPT 76362 without a large impact on median cost—even less if the cost of CPT 76362 was not packaged into the cost finding for the major procedure. This exception has a large effect on the number of single claims and cost finding for CPT 76362. In its published

materials, CMS reported a single claim count of 9 and an associated median cost finding of $371; if this exception is changed, TMC found 202 single claims with a cost finding of $580.

CONCLUSION

We respectfully request that CMS assign CPT 76362, CT guidance for tissue ablation, from APC 332 to a New Technology APC (1507). In addition we request that CMS consider placing CPT 76362 on the By Pass List in future ye ars. We appreciate the opportunity to offer our comments and would welcome an opportunity to meet with you and provide additional data to assist CMS in refining the OPPS specific to CT guidance for tissue ablation.

Sincerely,

/s/

Gary V. Delhougne JD, MHA
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Submitter : **Dr. Betty Welch** **Date: 09/15/2005**

Organization : **Elliot Hospital**

Category : **Hospital**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1501-P-466-Attach-1.DOC

September 15, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Md. 21244-1850

Re: Partial Hospitalization Service Proposed Changes to the Hospital Outpatient PPS-CMS-1501-P

Elliot Hospital is a hospital and psychiatric provider in New Hampshire. As a long-standing provider of Partial Hospitalization services, the initial shock of CMS-1501-P and a 15% rate reduction for CY2006 was overwhelming. The very existence of this service will be threatened for the future if our facility must absorb this amount of revenue reduction. It is very difficult to convince boards and administrative authorities to continue programs year after year on a break-even basis at best. A $40/day reduction will be an impossible task. CMS must reconsider this position or many facilities will have to take drastic action, which will likely cause many programs to close or to be severely limited.

As a member of the Association of Ambulatory Behavioral Healthcare, our organization stands firmly behind the comments they submitted. In addition, the following key points represent views that we see differently than CMS:

1. CMS-1501-P refers to the CY2005 combined hospital-based and CMHC median per diem costs of $289.00. As a facility, our costs increased in virtually every area including salaries, benefits, supplies, insurance, dietary support, communications and administrative support. We experienced overall increases in expenses of more than 5% in most areas. A daily per diem of $241.57 cannot be justified with these expenses.

2. CMS identified the Median cost of group therapy at $82.31. Our program offers 4 services per day at a minimum. This summarizes to a median cost of $329.24. A per diem of $241.57 cannot be justified with these expenses.

3. Many of our patients are Medi-Medi's. Medicaid cuts are strongly threatened here in New Hampshire. If the 20% copay is unavailable, the per diem would shrink even further and eliminate any consideration for these programs to exist. This would virtually reduce the per diem to $193.26 ($241.57 x .80). A daily per diem of $241.57 cannot be justified with this situation.

4. Cost reports are never settled in a timely fashion to include in your figures for the current per diem calculations. This can only artificially lower the actual median costs. When cost reports are settled, generally two years or more after the actual year of service, we have operated on actual revenues of 80% of the per diem. Facilities cannot operate by providing interest-free loans for two-year periods.

5. Based on the above issues, Elliot Hospital asks that CMS leave the per diem unchanged from the CY 2005 rate of $281.33. The proposed rate is not sufficient to cover the costs needed for our intensive program.

   If rates are slashed and our program cannot continue, the inpatient demands will grow substantially as there are no other alternative services for this needy population in our community. Our PHP program has had 121 admissions so far in CY 2006, and every one would be a high risk candidate for inpatient admission without the PHP availability.

   Thank you for your consideration of our comments. We look forward to your response and hope that with your support we can continue to make partial hospital services available for the beneficiaries who require this level of care.

   Sincerely,

   Betty Welch, Ph.D.
   Department Director
   Folkways Geropsychiatric Partial Hospitalization Program

Submitter : Mr. Gary Delhougne **Date:** 09/15/2005

Organization : Tyco Healthcare / Valleylab

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-467-Attach-1.DOC

tyco / Healthcare / Valleylab

September 15, 2005

Submitted Electronically to: www.cms.hhs.gov/regulations/ecomments
Submitted via Federal Express

Mark B. McClellan, M.D., Ph.D.
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington DC 20201

Re: CMS-1501-P
Medicare Program: Hospital Outpatient Prospective Payment System and Calendar year 2006 Payment Rates; Proposed Rule

Dear Dr. McClellan:

Valleylab, a division of Tyco Healthcare Group L P, is submitting these comments in response to the August 25, 2005 proposed rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates. Valleylab is a developer, manufacturer, marketer, and distributor of devices used for r adiofrequency ablation o f t umors. V alleylab is s ubmitting c omments s pecific t o Section III "**New Technology APCs**".

Comment

Valleylab respectfully requests that CMS reassign CPT 20982 (Ablation, bone tumor(s) radiofrequency, percutaneous, including CT guidance) from APC 1557 New Technology Level XX to APC 1559 New Technology Level XXII.

INTRODUCTION TO RADIOFREQUENCY ABLATION

Radiofrequency ablation involves the percutaneous, laparoscopic, or intraoperative insertion of an electrode into a lesion or tumor with the assistance of imaging guidance. Radiofrequency energy is emitted through the electrode to generate heat, leading to coagulative necrosis of the lesion or tumor.

CURRENT STATUS OF CPT 20982

Percutaneous Radiofrequency ablation of bone tumors with CT guidance was introduced as a CPT code in 2004. Currently CPT 20982 is assigned to a New Technology APC, 1557. The recently published Outpatient Prospective Payment System (OPPS) Proposed Rule of August 25, 2005 retains CPT 20982 in APC 1557 with an unchanged payment rate of $1,850. It has been reported to Valleylab by our outpatient facility customers that the payment rate for the procedure does not cover their costs. It is apparent that CPT 20982 should be reassigned to a higher paying New Technology APC.

DATA SUPPORTING COMMENT

Prior to 2004 no code or paid claims data were present to assist CMS in deciding which New Technology APC to assign CPT 20982. However, in calendar year 2004 paid claims data is available as well as the Direct Practice Expense Values Used to Create Resource-Based Practice Expense Relative Value Units data.

While we understand that CMS does not usually take into consideration non-claims related data, a review of the recently submitted and publicly available practice expense data demonstrates that the actual cost to perform the procedure far surpasses the payment rate of APC 1557. The practice expense submitted by the physicians references the costs of the procedure broken out into Equipment and Supply costs and the clinical staff time required to perform the procedure.

The costs of the supplies to perform the bone tumor ablation procedure are considerable. As shown in Attachment A, the total cost of all supplies necessary to perform the procedure is $2,113. Plainly, many supply costs are insignificant but the radiofrequency device technology cost is significant and all radiofrequency devices can only be used once.

Additionally, 2004 claims data identifies that two of the sixteen Single Frequency claims for CPT 20982 did not include a charge for an ablation device. Attachment B of this comment contains a report completed by the Moran Company analyzing the claims data for CPT 20982. The two claims out of sixteen missing a supply cost have a significant impact on the Median Cost of a CPT when the CPT's procedure supply cost is overwhelmingly determined by the ablation device (Approximately $2,000 per Attachment A). Supplementing the cost data of the Practice Expense survey, Moran's analysis of CMS claims data arrives at a total median cost of the procedure at $2,156.

It is estimated by the practice expense data report that nearly five hours of clinical staff time is used to assist the physicians in performing the bone tumor ablation procedure. First, the physician r equires the a ssistance of CT technologist for the d uration of the procedure, averaging 152 minutes. Second, the physician requires the assistance of a dedicated RN during the actual procedure for 97 minutes. Finally, the physician requires the assistance of other clinical staff before and during the procedure for 37 minutes. (See Attachment C)

Finally, the costs of the equipment required to perform the bone tumor ablation procedure are considerable. As shown in Attachment D, the costs of the equipment are considerable even when the price of the equipment is spread out over time and procedures.

CONCLUSION

Aggregating the costs of equipment, supplies, and clinician time demonstrates that the payment rate for APC 1557 does not adequately cover the costs of the procedure (See Attachment E). It is apparent that CPT 20982 was assigned to APC 1557 based on inadequate information. The current payment for APC 1557 does not even meet the costs of supplies for the procedure let alone the inclusion of equipment and clinician time. We respectfully request that CMS reassign CPT 20982 from APC 1557 to APC 1559.

We appreciate the opportunity to offer our comments and would welcome an opportunity to meet with you and provide additional data to assist CMS in refining the OPPS specific to radiofrequency ablation of liver tumors.

Sincerely,

/s/

Gary V. Delhougne JD, MHA
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EXTERNAL DATA FOR RECONSIDERATION OF APC ASSIGNMENT FOR CPT 20982

Attachment A

CPT 20982: BONE TUMORE ABLATION, RF, PERC, W/ CT GUIDANCE
RUC SUPPLY COST REPORT
FOR CALENDAR YEAR 2006

HCPCS	Source	Description	UNIT_05	QTY_05	Price	QTY_NF	Cost-NF
20982	RUC	probe, radiofrequency, 3 array (StarBurstSDE)	item	1	**1995**	1	**1995**
20982	RUC	cautery, patient ground pad w-cord	item	1	**3.07**	1	**3.07**
20982	RUC	scalpel with blade, surgical (#10-20)	item	1	**0.694**	1	**0.694**

20982	RUC	drape, sterile, fenestrated 16in x 29in	item	1	**0.557**	**1**	**0.557**
20982	RUC	drape, sterile, three-quarter sheet	item	1	**3.83**	**1**	**3.83**
20982	RUC	drape-towel, sterile 18in x 26in	item	1	**0.282**	**4**	**1.128**
20982	RUC	gloves, sterile	pair	1	**0.84**	**2**	**1.68**
20982	RUC	gown, surgical, sterile	item	1	**4.671**	**2**	**9.342**
20982	RUC	mask, surgical, with face shield	item	1	**1.199**	**3**	**3.597**
20982	RUC	shoe covers, surgical	pair	1	**0.338**	**3**	**1.014**
20982	RUC	underpad 2ft x 3ft (Chux)	item	1	**0.23**	**1**	**0.23**
20982	RUC	needle, 18-27g	item	1	**0.089**	**2**	**0.178**
20982	RUC	syringe 10-12ml	item	1	**0.184**	**1**	**0.184**
20982	RUC	syringe 20ml	item	1	**0.558**	**1**	**0.558**
20982	RUC	kit, radiofrequency introducer	kit	1	**50**	**1**	**50**
20982	RUC	pack, conscious sedation	pack	1	**17.311**	**1**	**17.311**
20982	RUC	pack, minimum multi-specialty visit	pack	1	**1.143**	**1**	**1.143**
20982	RUC	tray, biopsy procedure	tray	1	**14.65**	**1**	**14.65**
20982	RUC	tray, shave prep	tray	1	**1.812**	**1**	**1.812**
20982	RUC	cup, biopsy-specimen sterile 4oz	item	1	**0.173**	**1**	**0.173**
20982	RUC	cup-container, sterile, graduated 1000ml	item	1	**1.14**	**1**	**1.14**
20982	RUC	povidone soln (Betadine)	ml	1	**0.008**	**60**	**0.48**
20982	RUC	silver nitrate applicator	item	1	**0.07**	**1**	**0.07**
20982	RUC	tincture of benzoin, swab	item	1	**0.32**	**1**	**0.32**
20982	RUC	lidocaine 1%-2% inj (Xylocaine)	ml	1	**0.035**	**10**	**0.35**
20982	RUC	sodium chloride 0.9% irrigation (500-1000ml uou)	item	1	**2.074**	**1**	**2.074**
20982	RUC	applicator, sponge-tipped	item	1	**0.139**	**4**	**0.556**
20982	RUC	gauze, sterile 4in x 4in	item	1	**0.159**	**3**	**0.477**
20982	RUC	steri-strip (6 strip uou)	item	1	**1.116**	**1**	**1.116**
20982	RUC	tape, surgical paper 1in (Micropore)	inch	1	**0.002**	**12**	**0.024**
						TOTAL SUPPLY COST:	**$ 2,112.76**

Attachment B

THE MORAN COMPANY

HCPCS	Procedure Charge	Procedure Cost	Supply Charge	Supply Cost	Total Charge	Total Cost
Single Claims 20982						
Count	16	16	14	14	16	16
Min	$260.00	$182.13	$131.00	$5.04	$1,013.00	$338.57
Max	$6,825.00	$2,924.91	$8,234.80	$1,318.04	$22,517.30	$3,710.44
Mean	$2,988.00	$1,008.59	$2,164.35	$551.80	$7,401.22	$2,136.20
Median	$2,618.00	$755.72	$1,910.25	$569.15	$6,025.49	$2,155.74

Attachment C

CPT 20982: ABLATION BONE TUMOR(S), RF, PERC, W/ CT GUIDANCE
RUC TIME ESTIMATE REPORT
FOR CALENDAR YEAR 2006

HCPCS	Source	Description	Rate	Pre-Time NF	Intra-Time NF	Post-Time NF	
20982	RUC	CT Technologist	0.46	6	152	0	
20982	RUC	RN	0.51	0	97	0	
20982	RUC	RN/LPN/MTA	0.37	11	26	0	
				17	**275**	**0**	**292**

Total Nonfacility Support Staff Time: 4 hours 52 minutes

Attachment D

CPT 20982: ABLATION BONE TUMOR(S), RF, PERC, W/ CT GUIDANCE
RUC EQUIPMENT COST REPORT
FOR CALENDAR YEAR 2006

HCPCS	Source	Equip_Code	Description	LIFE	PRICE	Equip_Category_05
20982	RUC	EQ010	ECG, 3-channel	7	**1845.42**	OTHER EQUIPMENT
20982	RUC	EQ032	IV infusion pump	10	**2384.45**	OTHER EQUIPMENT
20982	RUC	EQ106	drill system, surgical, large (Stryker)	10	**15933**	OTHER EQUIPMENT
20982	RUC	EQ168	light, exam	10	**1630.12**	OTHER EQUIPMENT

20982	RUC	EQ211	pulse oximeter w-printer	7	**1207.18**	OTHER EQUIPMENT
20982	RUC	EQ214	radiofrequency generator (NEURO)	5	**32900**	OTHER EQUIPMENT
20982	RUC	ER005	IMRT CT-based simulator	5	**975000**	IMAGING EQUIP
20982	RUC	EF018	stretcher	10	**1915**	FURNITURE
		TOTAL EQUIPMENT COST:			**$1,032,815.17**	

Attachment E

CPT 20982: ABLATION, BONE TUMOR(S), RF, PERC, w/ CT GUIDANCE
RUC SUMMARY REPORT
FOR CALENDAR YEAR 2006

HCPCS	Pre-Time NF	Intra-Time NF	Supply Cost NF	Equip Cost NF
20982	6.83	129.01	2112.758	666.1829195

Total Salary Cost:	**$ 135.84**	
Total Supply Cost:	**$ 2,112.76**	
	$ 2,248.60	**Estimate Total Supply & Personel Cost**
Total Equipment Cost:	**$ 666.18**	

Submitter : Dr. Terry Portis

Date: 09/15/2005

Organization : Self Help for Hard of Hearing People (SHHH)

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Self Help for Hard of Hearing People (SHHH) submits the following comments (see attachment).

CMS-1501-P-468-Attach-1.DOC

September 16, 2005

Via Electronic Submission

The Honorable Mark B. McClellan, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule; (70 Federal Register 42674), July 25, 2005 (CMS-1501-P)

Dear Dr. McClellan:

Self Help for Hard of Hearing People (SHHH) respectfully submits our comments related to CMS-1501-P, proposed changes to OPPS and 2006 payment rates for services provided in the outpatient hospital setting. For our members who have hearing loss, the most significant among these proposed changes is the payment rate for cochlear implantation. Cochlear implant surgery is the only procedure in APC 0259. In 2005, the baseline payment rate for APC 0259 is $23,507. In 2006, the proposed baseline payment rate is $21,739.

In the last 12 months CMS has carefully considered CI payment rates, and also criteria for cochlear implantation. These previous considerations have benefited adults with significant hearing loss, and allowed them to have greater independence and quality of life. We were surprised to see these proposed changes to the payment rate.

Underpayment for this procedure will have negative effects on people with hearing loss who are Medicare recipients on several levels. One of the overlooked negative consequences is the potential to see existing cochlear implant clinics closed and potential cochlear implant clinics never open. This would limit access for seniors who are in need of this procedure.

Convenience to seniors of having a cochlear implant clinic nearby is critical during the first year after activation of the cochlear implant. A successful outcome for cochlear implantation is largely dependent on the programming and rehabilitation that occurs after surgery and device activation. A senior adult is less likely to follow through with their rehabilitation program if a cochlear implant center is not convenient to their residence.

Cochlear implantation is an important procedure that has demonstrated positive outcomes for its recipients. We ask that CMS give all due consideration to having a payment rate that is no lower than the 2005 rate, and allows for inflationary variables as well.

We appreciate your attention to this matter.

Sincerely,

Terry D. Portis, Ed.D.
Executive Director
Self Help for Hard of Hearing People (SHHH)

Submitter : Mr. Gary Delhougne **Date:** 09/15/2005

Organization : Tyco Healthcare / Valleylab

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-469-Attach-1.DOC

Submitter : Mrs. Jennifer Kimberling **Date:** 09/15/2005

Organization : Caritas Wound Healing Center

Category : Nurse Practitioner

Issue Areas/Comments

GENERAL

GENERAL

I am submitting this public comment to bring to your attention an error in the proposed rule, CMS-1501-P, ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates? relating to the payment rates for the wound-healing products Apligraf (C1305) and Dermagraft (C9201). These products have been paid in the hospital outpatient prospective payment system as specified covered outpatient drugs and should continue to be paid in 2006 similar to other such drugs. Patient access to these important products is jeopardized by the payment rates in the proposed rule. We respectfully request that the payment rates for Apligraf and Dermagraft be corrected in the final rule. Apligraf and Dermagraft are unique living human tissue substitutes for the treatment of chronic ulcers. Randomized prospective clinical trials have demonstrated the efficacy of these products to accelerate and support healing of chronic diabetic foot ulcers (Apligraf and Dermagraft) and venous leg ulcers (Apligraf) preserving and improving the quality of life of thousands of diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Many of these patients would have had to undergo limb amputations without the benefits of Apligraf and Dermagraft. In the proposed Hospital Outpatient Rule for calendar year 2006 the Centers for Medicare and Medicaid Services proposed to pay specified covered outpatient drugs at average sales price (ASP) plus six percent for the acquisition cost of the drug. The rule proposes to pay a pharmacy overhead charge of an additional two percent which results in a total payment for specified covered outpatient drugs of ASP plus eight percent. In 2002 both Apligraf and Dermagraft were paid as a biological under the pass through list. Following the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, both products have been paid for as sole-source biologicals in 2004 and in 2005 under the specified covered outpatient drug provision. Both products were included in the General Accountability Office (GAO) survey of acquisition costs for specified covered outpatient drugs dated June 30, 2005 (GAO-05-581R). The GAO report included the relevant ASP rates for each product. However, in the proposed rule both Apligraf and Dermagraft would be incorrectly paid based on rates derived from claims data in stead of payment at ASP plus eight percent. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product. Accordingly, both products experienced a significant decrease in payment: Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84 and Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32. There may have been some confusion in the proposed rule because the products are reimbursed in the physician?s office under codes with different descriptors. In the physician office setting, Apligraf and Dermagraft have been paid based on the ASP + six percent methodology under J7340 (Metabolic active Dermal/Epidermal tissue) and J7342 (Metabolically active Dermal tissue) respectively. I petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule.

tyco / Healthcare / Valleylab

September 15, 2005

Submitted Electronically to: www.cms.hhs.gov/regulations/ecomments
Submitted via Federal Express

Mark B. McClellan, M.D., Ph.D.
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Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington DC 20201

Re: CMS-1501-P
Medicare Program: Hospital Outpatient Prospective Payment System and Calendar year 2006 Payment Rates; Proposed Rule

Dear Dr. McClellan:

Valleylab, a division of Tyco Healthcare Group L P, is submitting these comments in response to the August 25, 2005 proposed rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates. Valleylab is a developer, manufacturer, marketer, and distributor of devices for radiofrequency ablation. Valleylab is submitting comments specific to Section III **"2 Times Rule"**.

Comment

Valleylab respectfully requests that CMS reassign CPT 47370 Laparoscopic radiofrequency ablation of liver tumors from APC 131 Level II Laparoscopy to APC 132 Level III Laparoscopy or in the alternative create a new Level IV Laparoscopy APC for laparoscopic ablation procedures.

INTRODUCTION TO RADIOFREQUENCY ABLATION

Radiofrequency ablation involves the percutaneous, laparoscopic, or intraoperative insertion of an electrode into a lesion or tumor with the assistance of imaging guidance. Radiofrequency energy is emitted through the electrode to generate heat, leading to coagulative necrosis of the lesion or tumor.

CURRENT STATUS OF CPT 47370

Laparoscopic radiofrequency ablation of liver tumors was introduced as a CPT code in 2002. Currently, CPT 47370 is assigned to APC 131 Level II Laparoscopy. The recently published Outpatient Prospective Payment System (OPPS) Proposed Rule of August 25, 2005 retains CPT 47370 in APC 131 with a payment rate of $2,572. It has been reported to Valleylab by our outpatient facility customers that the payment rate for the laparoscopic procedure does not cover their costs. It is apparent that CPT 47370 should be reassigned to a higher existing Laparoscopy APC, or be assigned to a newly created Laparoscopy APC.

DATA SUPPORTING COMMENT

Accompanying the Proposed Rule, the Median Cost for Hospital Outpatient Services File (Median Cost File) contains the data CMS used to establish APC 131's payment rate for 2006. A closer look at the data, and a review of Median Cost File data from 2003 and 2002, demonstrates that laparoscopic radiofrequency ablation of liver tumors, CPT 47370, requires resources outside the intention of APC 131 Level II Laparoscopy.

Annually CMS reviews APC groups to determine if services contained within a specific APC are no longer resource homogenous to its current CPT cohort. It is our belief that CPT 47370 is not resource homogenous to the other codes populating APC 131 because it is more than "two times greater than the median of the lowest cost item or service within the same group ("2 times rule").

Median Cost File data from 2004, 2003, and 2002 demonstrates that CPT 47370 is more than, and has been more than, "two times greater than the median of the lowest cost item or service" in APC 131. Additionally, it has been more than two times the median cost of the seventeen lowest CPTs in APC 131 in 2004 (See Attachment A), more than two times the median cost of the nine lowest CPTs in 2003 (See Attachment B), and more than two times the median costs of the five lowest CPTs in 2002 (See Attachment C).

In addition to CPT 47370's Median Cost data greater similarity to APC 132 than APC 131, its Single Frequency claims data is similar to two of the CPTs 38571 and 58550 of APC 132. To eliminate CPT 47370 from consideration would ignore the fact that in 2004 CPTs 38571 and 58550 of APC 132 both have comparable Single Frequency claim data, 44 and 32, respectively, as CPT 47370 (See Attachment A).

Though it may be argued that CPT 47370 lacks sufficient Single Frequency claims data to meet CMS's criteria for applying the two times rule, to do so would ignore the consistency apparent in the claims data over the past three years. From 2002 to 2004 its Median Cost has increased steadily by 24 percent from 2002 to 2003 and 15 percent from 2003 to 2004 (See Attachments A,B,C, & D). Its Single Frequency claims data doubled from 13 in 2002 to 26 in 2003, remaining at 26 in 2004 as well (See Attachment A,B,C, and D).

CONCLUSION

We respectfully request that CMS reassign CPT 47370, Laparoscopic radiofrequency ablation of liver tumors, from APC 131 Level II Laparoscopy to APC 132 Level III Laparoscopy or create a new Level IV Laparoscopic ablation code. We appreciate the opportunity to offer our comments and would welcome an opportunity to meet with you and provide additional data to assist CMS in refining the OPPS specific to radiofrequency ablation of liver tumors.

Sincerely,

/s/

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MEDIAN COST DATA

Attachment A

2004 Median Cost Data
0131 Level II Laparoscopy

CPT/ HCPCS	SI	APC	Payment	"Single" Frequency	Min Cost	Max Cost	Mean Cost	"True" Median Cost	CV
47370	T	0131	2571.86	26	2160.18	12916.65	6140.22	5402.24	50.323
38572	T	0131	2571.86	4	4132.29	5857.46	5029.31	5063.74	14.479
50947	T	0131	2571.86	2	1962.45	7692.80	4827.62	4827.62	83.933
38120	T	0131	2571.86	16	2504.42	6436.60	4554.47	4738.72	28.357
50543	T	0131	2571.86	7	3673.05	9082.88	5352.39	4690.23	38.165
58553	T	0131	2571.86	5	2571.01	7024.99	4065.60	3950.10	43.696
58554	T	0131	2571.86	8	332.47	6189.22	3747.84	3914.89	45.83
58552	T	0131	2571.86	151	1126.24	6919.68	3682.18	3687.83	33.501
50542	T	0131	2571.86	13	603.85	8249.60	3617.40	3401.55	62.514
47564	T	0131	2571.86	105	1105.69	7645.11	3344.04	3164.38	39.118
44970	T	0131	2571.86	358	770.25	6643.13	2966.09	2916.65	32.494
49651	T	0131	2571.86	1345	923.42	8948.98	3029.22	2865.39	36.095
38570	T	0131	2571.86	80	539.96	8324.50	3301.98	2815.30	45.498
49650	T	0131	2571.86	6536	862.60	8812.82	2955.88	2809.98	35.81
58673	T	0131	2571.86	3	2470.84	4585.32	3269.80	2753.25	35.109
47563	T	0131	2571.86	11693	904.79	7940.52	2848.63	2741.73	32.243
51990	T	0131	2571.86	36	909.10	5406.58	2733.73	2636.06	37.371

47562	T	0131	2571.86	33083	841.96	7495.99	2669.76	2543.18	33.013
44201	T	0131	2571.86	14	1462.60	5868.41	2859.86	2484.09	40.98
55550	T	0131	2571.86	7	608.55	3971.82	2343.45	2375.35	48.39
44200	T	0131	2571.86	403	874.55	7135.48	2510.72	2359.74	36.866
59151	T	0131	2571.86	12	1091.70	3840.63	2367.49	2274.94	31.285
58662	T	0131	2571.86	435	642.50	70.05	2335.10	2146.30	39.972
43653	T	0131	2571.86	28	342.56	4473.12	2259.56	2144.14	40.693
59150	T	0131	2571.86	1	2042.69	2042.69	2042.69	2042.69	.
58660	T	0131	2571.86	201	537.07	5600.09	2143.21	2038.58	40.396
50945	T	0131	2571.86	1	2028.39	2028.39	2028.39	2028.39	.
47371	T	0131	2571.86	2	1651.91	2162.97	1907.44	1907.44	18.945
58671	T	0131	2571.86	455	560.21	5462.36	1860.48	1741.24	36.023
58670	T	0131	2571.86	621	544.59	4229.25	1741.24	1658.03	34.902
58672	T	0131	2571.86	2	988.43	2185.64	1587.04	1587.04	53.342
54690	T	0131	2571.86	5	839.41	2790.63	1436.62	1134.48	53.891
58661	T	0131	2571.86	1996	773.12	9523.68	2960.29	28.42	36.627

0132 Level III Laparoscopy

CPT/ HCPCS	SI	APC	Payment	"Single" Frequency	Min Cost	Max Cost	Mean Cost	"True" Median Cost	CV
43280	T	0132	3738.10	666	1148.35	11312.61	4188.20	4089.13	33.895
38571	T	0132	3738.10	44	1879.65	8165.72	3810.55	3571.04	39.458
58550	T	0132	3738.10	32	640.34	7617.08	3573.58	3153.36	47.714
51992	T	0132	3738.10	124	1157.10	6036.52	2620.36	2527.25	32.216

Attachment B

2003 Median Cost Data

0131 Level II Laparoscopy

CPT/ HCPCS	APC	Payment	"Single" Frequency	Min Cost	Max Cost	Mean Cost	"True" median cost	CV
58554	0131	2436.17	9	1953.44	34351.47	8244.14	5607.95	120.141
47370	0131	2436.17	26	2173.63	10782.86	4876.28	4682.5	36.099
38120	0131	2436.17	27	2137.96	8080.62	4101.37	4059.47	31.016
58553	0131	2436.17	3	946.83	6474.87	3758.41	3853.52	73.575
58552	0131	2436.17	93	1801.48	6129.98	3658.41	3662.66	28.394
50543	0131	2436.17	3	818.39	4689.34	3046.9	3632.98	65.671
58672	0131	2436.17	1	3248.52	3248.52	3248.52	3248.52	.
47564	0131	2436.17	121	881.54	11492.35	3330.87	3108.22	45.445
58546	0131	2436.17	1	3067.98	3067.98	3067.98	3067.98	.
38572	0131	2436.17	5	554.12	3147.04	2340.26	2937.46	46.361
59151	0131	2436.17	15	1950.97	5266.66	3208.81	2933.57	27.825
44970	0131	2436.17	306	939.06	6695.92	2876.11	2809.8	32.644
55550	0131	2436.17	5	1307.29	5026.94	2921.49	2779.06	49.272
49651	0131	2436.17	1245	873.01	8518	2887.9	2758.43	36.461
58661	0131	2436.17	1962	775.1	9040.67	2877.39	2741.49	37.97

51990	0131	2436.17	60	1519.76	5768.4	2733.91	2703.91	33.529
47563	0131	2436.17	9740	900.06	7711.53	2790.81	2656.95	32.725
49650	0131	2436.17	6054	770.28	8803.78	2827.49	2655.08	36.633
58673	0131	2436.17	2	2042.66	3199.8	2621.23	2621.23	31.215
38570	0131	2436.17	78	1079.13	6012.63	2714.27	2594.89	34.95
58551	0131	2436.17	2	861.57	4217.67	2539.62	2539.62	93.444
59150	0131	2436.17	3	2199.08	2949.95	2537.67	2463.97	15.007
50542	0131	2436.17	11	592.74	6716.58	2828.5	2459.14	62.154
47562	0131	2436.17	32878	809.1	7265	2564.08	2445.09	32.749
44200	0131	2436.17	383	774.81	9777.15	2312.53	2141.73	40.511
58662	0131	2436.17	479	625.66	6751.75	2257.49	2106.62	38.634
58660	0131	2436.17	244	676.27	6903.09	2294.91	2053.95	45.062
44201	0131	2436.17	18	262.04	4052.64	1821.32	1639.47	56.779
58671	0131	2436.17	488	658.24	4508.18	1732.73	1615.76	35.008
58670	0131	2436.17	683	490.75	6085.75	1703.77	1579.64	38.114
43653	0131	2436.17	23	96.53	4960.48	1674.49	1535.45	77.365
50947	0131	2436.17	3	65.11	1402.31	907	1253.57	80.803
54690	0131	2436.17	9	684.15	3160.19	1685.64	1211.22	51.784

0132 Level III Laparoscopy

CPT/ HCPCS	APC	Payment	"Single" Frequency	Min Cost	Max Cost	Mean Cost	"True" median cost	CV
43280	0132	3494.24	719	1156.5	12664.8	4067.91	3924.03	37.487
58550	0132	3494.24	65	1153.51	7300.39	3597.84	3475.83	35.188
38571	0132	3494.24	63	1501.69	5856.72	3092.9	3004.29	35.062
43652	0132	3494.24	1	2737.49	2737.49	2737.49	2737.49	.
51992	0132	3494.24	122	905.15	4874.82	2432.39	2435.43	33.752

Attachment C

2002 Median Cost Data

0131 Level II Laparoscopy

CPT/ HCPCS	APC	Single Claims Freq	Total Cost	Minimum	Maximum	Mean of Total Cost	(True) Median of Total Cost	CV
38120	0131	14	65423.85	1392.27	10508.72	4673.13	4676.43	53.185
47370	0131	13	67835	1968.56	13100.19	5218.08	3765.05	64.699
49659	0131	1033	3684142.7	273.87	12476.39	3566.45	3350.36	42.435
38572	0131	4	13345.56	2231.68	5575.48	3336.39	2769.2	45.656
55550	0131	1	2707.81	2707.81	2707.81	2707.81	2707.81	
49651	0131	812	2323203.7	776.78	9999.29	2861.09	2616.93	42.86
58551	0131	10	32134.14	1346.03	6351.79	3213.41	2607.95	53.872
58673	0131	3	7478.88	2310.04	2587.74	2492.96	2581.1	6.356
58661	0131	1364	3727727.3	442.83	11840.08	2732.94	2536.8	41.717
51990	0131	51	126983.92	145.49	5200.64	2489.88	2529.34	39.056
49650	0131	3922	10462127	723.1	9364.51	2667.55	2527.49	37.806

59151	0131	4	9812.63	1983.33	2848.44	2453.16	2490.43	14.517
59150	0131	3	7498.79	2192.1	2831.49	2499.6	2475.2	12.818
47371	0131	3	15786.61	2193.89	11160.97	5262.2	2431.75	97.105
47564	0131	36	91276.65	191.68	5483.3	2535.46	2430.96	50.663
38570	0131	55	140126.88	632.59	5609.69	2547.76	2411.27	42.792
47563	0131	1541	3623418.5	17.79	11629.92	2351.34	2378.55	53.126
47562	0131	23245	57840750	352.58	13627.74	2488.31	2337.48	37.133
44201	0131	10	24057.45	1015.46	4179.24	2405.75	2258.56	41.733
44200	0131	315	786120.47	345.86	17657.07	2495.62	2161.06	62.053
58662	0131	325	733408.1	613.68	9095.91	2256.64	2005.54	47.787
43653	0131	13	25075.27	73.11	4134.16	1928.87	1997.94	62.85
58660	0131	217	466000.34	695.23	4794.98	2147.47	1976.94	40.853
58672	0131	2	3280.69	1377.38	1903.31	1640.35	1640.35	22.671
58671	0131	335	558185.58	417.96	5357.43	1666.23	1584.69	38.989
58670	0131	465	761179.74	444.78	6096.37	1636.95	1492.51	42.847
54690	0131	8	10558.39	54.12	2632.38	1319.8	1255.27	74.497
50947	0131	1	1093.87	1093.87	1093.87	1093.87	1093.87	

0132 Level III Laparoscopy

CPT/HCPCS	APC	Single Claims Freq	Total Cost	Minimum	Maximum	Mean of Total Cost	(True) Median of Total Cost	CV
43280	0132	540	1998111.3	164.88	23402.91	3700.21	3531.17	48.302
58550	0132	156	526216.5	87.93	10962.55	3373.18	3411.48	44.357
38571	0132	49	141598.71	306.87	6355.01	2889.77	2895.51	40.924
51992	0132	113	265392.42	851.27	5313.78	2348.61	2254.68	33.19

Attachment D

CPT 47370 Laparoscopic Ablation Liver Tumor RF Median Cost Data Comparison 2002-2004

Pmt Yr	47370 Median Cost	Median Cost % Increase	APC 131 Unadj Pmt Rate	Difference	Claim Volume
2004	3,765.05		2,226.44	(1,538.61)	13
2005	4,682.50	24%	2,436.17	(2,246.33)	26
2006	5,402.24	15%	2,571.86	(2,830.38)	26

Pmt Yr	APC 132 Unadj Pmt Rate	Pmt Rate % Increase	APC 132 Pmt Rate / 47370 Median Cost	47370 % Higher than Top APC 132 CPT
2004	3121.13		83%	7%
2005	3494.24	12%	75%	19%
2006	3738.10	7%	69%	32%

Submitter : Mr. Gary Delhougne **Date:** 09/15/2005

Organization : Tyco Healthcare / Valleylab

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-471-Attach-1.DOC

tyco / Healthcare / Valleylab

September 15, 2005

Submitted Electronically to: www.cms.hhs.gov/regulations/ecomments
Submitted via Federal Express

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Washington DC 20201

Re: CMS-1501-P
Medicare Program: Hospital Outpatient Prospective Payment System and Calendar year 2006 Payment Rates; Proposed Rule

Dear Dr. McClellan:

Valleylab, a division of Tyco Healthcare Group L P, is submitting these comments in response to the August 25, 2005 proposed rule: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates. Valleylab is a developer, manufacturer, marketer, and distributor of devices for radiofrequency ablation. Valleylab is submitting comments specific to Section III **"2 Times Rule"**.

Comment

Valleylab respectfully requests that CMS reassign CPT 50542, Laparoscopic ablation of renal mass lesions, from APC 131 Level II Laparoscopy to APC 132 Level III Laparoscopy or in the alternative create a new Level IV Laparoscopy APC for laparoscopic ablation procedures.

INTRODUCTION TO RADIOFREQUENCY ABLATION

Radiofrequency ablation involves the percutaneous, laparoscopic, or intraoperative insertion of an electrode into a lesion or tumor with the assistance of imaging guidance. Radiofrequency energy is emitted through the electrode to generate heat, leading to coagulative necrosis of the lesion or tumor.

CURRENT STATUS OF CPT 50542

Laparoscopic ablation of renal mass lesions was introduced as a CPT code in 2003. Currently, CPT 50542 is assigned to APC 131 Level II Laparoscopy. The recently published Outpatient Prospective Payment System (OPPS) Proposed Rule of August 25, 2005 retains CPT 50542 in APC 131 with a payment rate of $2,572. It has been reported to Valleylab by our outpatient facility customers that the payment rate for the laparoscopic procedure does not cover their costs. It is apparent that CPT 50542 should be reassigned to a higher existing Laparoscopy APC, or be assigned to a newly created Laparoscopy APC.

DATA SUPPORTING COMMENT

Accompanying the Proposed Rule, the Median Cost for Hospital Outpatient Services File (Median Cost File) contains the data CMS used to establish APC 131's payment rate for 2006. A closer look at the 2004 Median Cost data (See Attachment A), and a review of Median Cost File data from 2003 (See Attachment B), demonstrates that laparoscopic ablation of renal mass lesions, CPT 50542, requires resources outside the intention of APC 131 Level II Laparoscopy.

Annually CMS reviews APC groups to determine if services contained within a specific APC are no longer resource homogenous to its current CPT cohort. It is our belief that CPT 50542 is not resource homogenous to the other codes populating APC 131 because it is more than "two times greater than the median of the lowest cost item or service within the same group ("2 times rule"). Median Cost File data from 2004 and 2003 demonstrates that CPT 50542 is more than, and has been more than, "two times greater than the median of the lowest cost item or service" in APC 131.

Though it may be argued that CPT 50542 lacks sufficient Single Frequency claims data to meet CMS's criteria for applying the two times rule, to do so would ignore the consistency apparent in the claims data over the past three years. From 2003 to 2004 its Median Cost has increased from $2,459 to $3,402. Its Single Frequency claims data increased to 13 in 2004 from 11 in 2003. To eliminate CPT 50542 from consideration would ignore the fact that in 2004 CPTs 38571 and 58550 of APC 132 both have comparable Single Frequency claim data, 44 and 32, respectively, as CPT 50542.

Additionally, 2004 claims data identifies that two of the eleven Single Frequency claims for CPT 50542 did not include a charge for an ablation device. Attachment C of this comment contains a report completed by the Moran Company analyzing the claims data for CPT 50542. The two claims out of eleven missing a supply cost have a significant impact on the Median Cost of a CPT when the CPT's procedure supply cost is overwhelmingly determined by the ablation device (Approximately $2,000 per the Physician Practice Expense Survey using CPT 20982 as a benchmark for the cost of an ablation device.)

CONCLUSION

We respectfully request that CMS reassign CPT 50542, Laparoscopic ablation of renal mass lesions, from APC 131 Level II Laparoscopy to APC 132 Level III Laparoscopy.

We appreciate the opportunity to offer our comments and would welcome an opportunity to meet with you and provide additional data to assist CMS in refining the OPPS specific to the ablation of renal mass lesions.

Sincerely,

/s/

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MEDIAN COST DATA

Attachment A

2004 Median Cost Data
0131 Level II Laparoscopy

CPT/ HCPCS	SI	APC	Payment	"Single" Frequency	Min Cost	Max Cost	Mean Cost	"True" Median Cost	CV
47370	T	0131	2571.86	26	2160.18	12916.65	6140.22	5402.24	50.323
38572	T	0131	2571.86	4	4132.29	5857.46	5029.31	5063.74	14.479
50947	T	0131	2571.86	2	1962.45	7692.80	4827.62	4827.62	83.933
38120	T	0131	2571.86	16	2504.42	6436.60	4554.47	4738.72	28.357
50543	T	0131	2571.86	7	3673.05	9082.88	5352.39	4690.23	38.165
58553	T	0131	2571.86	5	2571.01	7024.99	4065.60	3950.10	43.696
58554	T	0131	2571.86	8	332.47	6189.22	3747.84	3914.89	45.83
58552	T	0131	2571.86	151	1126.24	6919.68	3682.18	3687.83	33.501
50542	T	0131	2571.86	13	603.85	8249.60	3617.40	3401.55	62.514
47564	T	0131	2571.86	105	1105.69	7645.11	3344.04	3164.38	39.118
44970	T	0131	2571.86	358	770.25	6643.13	2966.09	2916.65	32.494
49651	T	0131	2571.86	1345	923.42	8948.98	3029.22	2865.39	36.095
38570	T	0131	2571.86	80	539.96	8324.50	3301.98	2815.30	45.498
49650	T	0131	2571.86	6536	862.60	8812.82	2955.88	2809.98	35.81
58673	T	0131	2571.86	3	2470.84	4585.32	3269.80	2753.25	35.109
47563	T	0131	2571.86	11693	904.79	7940.52	2848.63	2741.73	32.243
51990	T	0131	2571.86	36	909.10	5406.58	2733.73	2636.06	37.371
47562	T	0131	2571.86	33083	841.96	7495.99	2669.76	2543.18	33.013
44201	T	0131	2571.86	14	1462.60	5868.41	2859.86	2484.09	40.98
55550	T	0131	2571.86	7	608.55	3971.82	2343.45	2375.35	48.39

44200	T	0131	2571.86	403	874.55	7135.48	2510.72	2359.74	36.866
59151	T	0131	2571.86	12	1091.70	3840.63	2367.49	2274.94	31.285
58662	T	0131	2571.86	435	642.50	70.05	2335.10	2146.30	39.972
43653	T	0131	2571.86	28	342.56	4473.12	2259.56	2144.14	40.693
59150	T	0131	2571.86	1	2042.69	2042.69	2042.69	2042.69	.
58660	T	0131	2571.86	201	537.07	5600.09	2143.21	2038.58	40.396
50945	T	0131	2571.86	1	2028.39	2028.39	2028.39	2028.39	.
47371	T	0131	2571.86	2	1651.91	2162.97	1907.44	1907.44	18.945
58671	T	0131	2571.86	455	560.21	5462.36	1860.48	1741.24	36.023
58670	T	0131	2571.86	621	544.59	4229.25	1741.24	1658.03	34.902
58672	T	0131	2571.86	2	988.43	2185.64	1587.04	1587.04	53.342
54690	T	0131	2571.86	5	839.41	2790.63	1436.62	1134.48	53.891
58661	T	0131	2571.86	1996	773.12	9523.68	2960.29	28.42	36.627

0132 Level III Laparoscopy

CPT/ HCPCS	SI	APC	Payment	"Single" Frequency	Min Cost	Max Cost	Mean Cost	"True" Median Cost	CV
43280	T	0132	3738.10	666	1148.35	11312.61	4188.20	4089.13	33.895
38571	T	0132	3738.10	44	1879.65	8165.72	3810.55	3571.04	39.458
58550	T	0132	3738.10	32	640.34	7617.08	3573.58	3153.36	47.714
51992	T	0132	3738.10	124	1157.10	6036.52	2620.36	2527.25	32.216

Attachment B

2003 Median Cost Data

0131 Level II Laparoscopy

CPT/ HCPCS	APC	Payment	"Single" Frequency	Min Cost	Max Cost	Mean Cost	"True" median cost	CV
58554	0131	2436.17	9	1953.44	34351.47	8244.14	5607.95	120.141
47370	0131	2436.17	26	2173.63	10782.86	4876.28	4682.5	36.099
38120	0131	2436.17	27	2137.96	8080.62	4101.37	4059.47	31.016
58553	0131	2436.17	3	946.83	6474.87	3758.41	3853.52	73.575
58552	0131	2436.17	93	1801.48	6129.98	3658.41	3662.66	28.394
50543	0131	2436.17	3	818.39	4689.34	3046.9	3632.98	65.671
58672	0131	2436.17	1	3248.52	3248.52	3248.52	3248.52	.
47564	0131	2436.17	121	881.54	11492.35	3330.87	3108.22	45.445
58546	0131	2436.17	1	3067.98	3067.98	3067.98	3067.98	.
38572	0131	2436.17	5	554.12	3147.04	2340.26	2937.46	46.361
59151	0131	2436.17	15	1950.97	5266.66	3208.81	2933.57	27.825
44970	0131	2436.17	306	939.06	6695.92	2876.11	2809.8	32.644
55550	0131	2436.17	5	1307.29	5026.94	2921.49	2779.06	49.272
49651	0131	2436.17	1245	873.01	8518	2887.9	2758.43	36.461
58661	0131	2436.17	1962	775.1	9040.67	2877.39	2741.49	37.97

51990	0131	2436.17	60	1519.76	5768.4	2733.91	2703.91	33.529
47563	0131	2436.17	9740	900.06	7711.53	2790.81	2656.95	32.725
49650	0131	2436.17	6054	770.28	8803.78	2827.49	2655.08	36.633
58673	0131	2436.17	2	2042.66	3199.8	2621.23	2621.23	31.215
38570	0131	2436.17	78	1079.13	6012.63	2714.27	2594.89	34.95
58551	0131	2436.17	2	861.57	4217.67	2539.62	2539.62	93.444
59150	0131	2436.17	3	2199.08	2949.95	2537.67	2463.97	15.007
50542	0131	2436.17	11	592.74	6716.58	2828.5	2459.14	62.154
47562	0131	2436.17	32878	809.1	7265	2564.08	2445.09	32.749
44200	0131	2436.17	383	774.81	9777.15	2312.53	2141.73	40.511
58662	0131	2436.17	479	625.66	6751.75	2257.49	2106.62	38.634
58660	0131	2436.17	244	676.27	6903.09	2294.91	2053.95	45.062
44201	0131	2436.17	18	262.04	4052.64	1821.32	1639.47	56.779
58671	0131	2436.17	488	658.24	4508.18	1732.73	1615.76	35.008
58670	0131	2436.17	683	490.75	6085.75	1703.77	1579.64	38.114
43653	0131	2436.17	23	96.53	4960.48	1674.49	1535.45	77.365
50947	0131	2436.17	3	65.11	1402.31	907	1253.57	80.803
54690	0131	2436.17	9	684.15	3160.19	1685.64	1211.22	51.784

0132 Level III Laparoscopy

CPT/ HCPCS	APC	Payment	"Single" Frequency	Min Cost	Max Cost	Mean Cost	"True" median cost	CV
43280	0132	3494.24	719	1156.5	12664.8	4067.91	3924.03	37.487
58550	0132	3494.24	65	1153.51	7300.39	3597.84	3475.83	35.188
38571	0132	3494.24	63	1501.69	5856.72	3092.9	3004.29	35.062
43652	0132	3494.24	1	2737.49	2737.49	2737.49	2737.49	.
51992	0132	3494.24	122	905.15	4874.82	2432.39	2435.43	33.752

Attachment C

THE MORAN COMPANY

HCPCS	Procedure Charge	Procedure Cost	Supply Charge	Supply Cost	Total Charge	Total Cost
Single Claims 50542						
Count	11	11	9	9	11	11
Min	$305.50	$172.94	$103.09	$14.57	2,515.50	1,117.64
Max	$8,552.00	$2,866.50	$16,887.33	$4,345.10	24,355.91	6,024.39
Mean	$3,967.66	$1,622.05	$5,267.96	$1,237.74	10,552.78	3,198.08
Median	$3,892.50	$1,673.38	$3,767.00	$1,109.38	9,869.64	3,327.46

Submitter : Dr. Rodney McMillin **Date:** 09/15/2005

Organization : Caritas Wound Healing Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I am submitting this public comment to bring to your attention an error in the proposed rule, CMS-1501-P, ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates? relating to the payment rates for the wound-healing products Apligraf (C1305) and Dermagraft (C9201). These products have been paid in the hospital outpatient prospective payment system as specified covered outpatient drugs and should continue to be paid in 2006 similar to other such drugs. Patient access to these important products is jeopardized by the payment rates in the proposed rule. We respectfully request that the payment rates for Apligraf and Dermagraft be corrected in the final rule. Apligraf and Dermagraft are unique living human tissue substitutes for the treatment of chronic ulcers. Randomized prospective clinical trials have demonstrated the efficacy of these products to accelerate and support healing of chronic diabetic foot ulcers (Apligraf and Dermagraft) and venous leg ulcers (Apligraf) preserving and improving the quality of life of thousands of diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Many of these patients would have had to undergo limb amputations without the benefits of Apligraf and Dermagraft. In the proposed Hospital Outpatient Rule for calendar year 2006 the Centers for Medicare and Medicaid Services proposed to pay specified covered outpatient drugs at average sales price (ASP) plus six percent for the acquisition cost of the drug. The rule proposes to pay a pharmacy overhead charge of an additional two percent which results in a total payment for specified covered outpatient drugs of ASP plus eight percent. In 2002 both Apligraf and Dermagraft were paid as a biological under the pass through list. Following the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, both products have been paid for as sole-source biologicals in 2004 and in 2005 under the specified covered outpatient drug provision. Both products were included in the General Accountability Office (GAO) survey of acquisition costs for specified covered outpatient drugs dated June 30, 2005 (GAO-05-581R). The GAO report included the relevant ASP rates for each product. However, in the proposed rule both Apligraf and Dermagraft would be incorrectly paid based on rates derived from claims data in stead of payment at ASP plus eight percent. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product. Accordingly, both products experienced a significant decrease in payment: Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84 and Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32. There may have been some confusion in the proposed rule because the products are reimbursed in the physician?s office under codes with different descriptors. In the physician office setting, Apligraf and Dermagraft have been paid based on the ASP + six percent methodology under J7340 (Metabolic active Dermal/Epidermal tissue) and J7342 (Metabolically active Dermal tissue) respectively. I petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule.

Submitter : **Ms. Linda Winger** **Date: 09/15/2005**

Organization : **Georgetown University Hospital**

Category : **Health Care Professional or Association**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1501-P-473-Attach-1.DOC

CYBERKNIFE
CKC
COALITION

Georgetown University Medical Center • Rocky Mountain CyberKnife Center
St. Joseph's Hospital, Member of HealthEast Care System
CyberKnife Center of Palm Beach • CyberKnife Center of Miami
South Texas Stereotactic Radiosurgery • Western Cancer Center, San Diego
Riverview Medical Center, a member of Meridian Health
CyberKnife Radiosurgery Center of Iowa

September 13, 2005

Reference file code: CMS-1501-P
Specific issue "Stereotactic Radiosurgery (SRS)"

Image-Guided Robotic Stereotactic Radiosurgery

On behalf of the CyberKnife Coalition, the consortium of healthcare providers across the country that provide image-guided robotic stereotactic radiosurgery (SRS) using CyberKnife® technology. I submit the following comments on image-guided robotic stereotactic radiosurgery APC groups and their associated weights.

In 2003, CMS established new HCPCS codes for image-guided robotic stereotactic radiosurgery to distinguish these services from other, older and nondedicated, linear accelerator-based (LINAC-based) stereotactic radiosurgery systems that are substantially less resource-intensive. We will offer comments and recommendations on each.

I. **Placement of Stereotactic Radiosurgery Treatment Delivery Code G0339 at APC 1528** for treatment complete in one session or first treatment of image-guided robotic stereotactic radiosurgery.

CMS established HCPCS G0339, which describes image-guided robotic LINAC-based stereotactic radiosurgery completed in one treatment session (or the first of multiple treatment sessions), and assigned this new code to New Technology APC 1528.

Image-guided robotic stereotactic radiosurgery is both an alternative to surgery and an adjunct to radiotherapy involving a defined set of clinical resources to deliver effective treatment. Image-guided robotic stereotactic radiosurgery is not radiotherapy as it is intended to ablate identifiable lesions rather than treat microscopic disease while preserving normal tissue adjacent to the target volume. Both clinicians and patients have recognized the benefits of radiosurgery which include no incisions, no anesthesia, lower risk of complications, and, therefore, improved patient quality of life.

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It was on the basis of cost that CMS established separate codes for image-guided robotic, non-gantry mounted, linear accelerator-based stereotactic radiosurgery as distinguished from older cobalt and predecessor systems. The capital and operating costs involved in the provision of image-guided robotic stereotactic radiosurgery are comparable to the costs involved in the provision of radiosurgery using the cobalt systems, and greater than those using predecessor linear accelerator-based systems. There are several clinical distinctions between the image-guided robotic stereotactic radiosurgery system, the cobalt radiosurgery systems, and predecessor linear accelerator-based systems;

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(1) Cobalt systems: While extremely precise, cobalt-based radiosurgery systems are limited by their very design, which includes rigid 4-point head fixation and helmet device configuration, to the treatment of intracranial lesions with a single fraction, delivered on the same day as the treatment planning session. The CyberKnife image-guided stereotactic radiosurgery system treats intracranial tumors with a level of clinical precision comparable to the Cobalt systems, but uses noninvasive radiologic target tracking instead of a rigid head frame, and without the confines of a "helmet" radiation delivery system. This means that the CyberKnife system is not constrained to accomplish the treatment planning and treatment on the same day, is not limited to a single fraction, and is not limited to intracranial lesions. Rather, the CyberKnife image-guided stereotactic radiosurgery system design allows the same treatment targeting methodology to be applied to lesions throughout the body.

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(2) Predecessor linear-accelerator-based systems: The CyberKnife image-guided stereotactic radiosurgery system automatically delivers non-coplanar, non-isocentric beams which minimize entrance and exit beam interactions so as to decrease dose accumulation away from the target volume. No patient or manual beam repositioning is needed to achieve non-coplanar beam delivery. CyberKnife was inherently designed with the capability to deliver non-isocentric, non-coplanar beams to maximize conformality, and represents a fundamental design difference from any other linear-accelerator-based system;

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(3) Predecessor linear-accelerator-based systems: Tracking: The CyberKnife image-guided stereotactic radiosurgery system employs a unique method of target tracking that updates the target lesion location and automatically positions the radiation beam with sub-millimeter accuracy throughout the entire treatment. The essence of this robotic radiosurgery system that differentiates it from all others to date is the virtually instantaneous and continuous feedback loop between X-ray based target localization and automatic correction of accelerator therapeutic radiation delivery throughout the entire treatment. The CyberKnife can dynamically target the tumor and adjust the beam to follow the motion of the lesion throughout the treatment, directing the beam to precisely match target lesion movement, enabling frameless radiosurgical treatment, and allowing radiosurgical accuracy to be extended to target lesions throughout the body, even though they are more prone to movement over the time of treatment compared with intracranial lesions. Continuous target lesion tracking and dynamic treatment correction also differentiates CyberKnife image-guided robotic stereotactic radiosurgery from intensity modulated radiation therapy (IMRT), by allowing subtraction of target lesion motion uncertainty in the design of the planning target volume (PTV), translating to the ability to more accurately encompass an entire target lesion with a much smaller margin, creating superior sparing of adjacent tissue, allowing the use of radiosurgical dose fractionation;

(4) Predecessor linear-accelerator-based systems: Synchrony Respiratory Tracking System: this represents a secondary CyberKnife target tracking mechanism that may be added to the basic tracking method described above, for target lesions that move with respiration. Synchrony software and hardware correlate externally detected respiratory body motion with internal target lesion motion, allowing the robotic stereotactic radiosurgery system to move the linear accelerator continuously, to track the target lesion as it moves throughout the respiratory cycle, with a total clinical accuracy of less than 1.5 mm. This level of accuracy in a moving lesion, for example a lung tumor, permits the Cyberknife to ablate the lesion with accuracy comparable to a conventional surgical approach. This real-time respiratory target lesion tracking capability further distinguishes the CyberKnife system from other systems.

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In summary, because of the attributes described above, the CyberKnife is a complex image-guided robotic stereotactic radiosurgery system, delivering radiosurgical precision throughout the body, for as many treatments (fractions) as the clinician deems necessary for a given situation. As indicated below, CMS currently allows for up to five fractionated image-guided robotic stereotactic radiosurgery treatments. Currently, our data indicate that treatments average 2.5 fractions per course of treatment.

Recommendation: The resources used for each image-guided robotic stereotactic radiosurgery treatment are consistent and APC 1528 generally captures the cost of the resources used to provide each treatment. We recommend that CMS makes G0339 image-guided robotic stereotactic radiosurgery a permanent code and create a permanent APC at the current APC 1528 rate for all treatments.

II. Placement of Stereotactic Radiosurgery Treatment Delivery Code *G0340 at APC 1525* for treatments 2-5, image-guided robotic stereotactic radiosurgery.

In 2003, CMS also established HCPCS G0340, which describes the second and any subsequent treatment sessions of stereotactic radiosurgery (up to five treatment sessions), and assigned this new code to New Technology APC 1525, with a rate that is approximately 70% of the rate for the first treatment.

The payment rate for G0340 (treatment sessions 2-5) is currently based on a percentage of the payment for a single session delivery, rather than the cost of resources for each treatment session. The treatment reimbursement does not reflect the consistent use of resources for each session. The current payment rate incorrectly assumes that the cost of a session is lower when multiple sessions are involved. In fact, the cost-per-session is the same regardless of the number of sessions involved, and we look forward to continuing to work with CMS to establish accurate cost data for all treatment sessions.

The Hospital Outpatient Prospective Payment System (HOPPS) was intended by Congress to be resource-based, as reflected in hospital cost and charge data. Although the first-year charge data for G0340, APC 1525, do not fully demonstrate the consistency of costs across sessions, we believe that most of the discrepancy is attributable to first-year confusion on the part of billers.

We recognize that some have charged that the current payment rates create inappropriate financial incentives. However, inappropriate incentives are created only if the rate substantially exceeds the costs involved. If actual costs (including both fixed and variable) exceed the payment rate, the payment system does not create an inappropriate payment incentive. To the contrary, the establishment of a lower rate would create an inappropriate payment disincentive making it financially prohibitive for institutions to make this technology available to their patients. Further, the decision to give single versus multiple treatments (fractions) is made by the clinician(s), while the payment codes under discussion reimburse the facility for its resource-based cost, meaning there is no link between fractionation and financial reward to the fractionation decision maker from facility reimbursement codes discussed herein.

There is no question that image-guided robotic stereotactic radiosurgery is substantially more resource-intensive than other forms of LINAC-based systems. In fact, it was for this reason that CMS created separate HCPCS codes to distinguish these technologies. Further, it is clear that the resources required for image-guided robotic stereotactic radiosurgery treatment are the same regardless of whether the treatment is performed in the first or a subsequent session.

Recommendation: We recommend that CMS eliminate G0340 (APC 1525) and modify the descriptor for G0339 (APC 1528) to include all CyberKnife treatment sessions.

III. ***G0338*** at ***APC 1516,*** *linear* accelerator-based stereotactic radiosurgery planning.

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We agree with the recommendation of CMS staff to eliminate G0338 and to authorize hospitals to use the applicable treatment planning codes. Providers routinely use the treatment planning codes for a broad array of radiation oncology services and are therefore familiar with them. Elimination of the planning code G0338 will enable hospitals to use these codes without being concerned about whether a particular planning code has been "bundled" into G0338 and will enable hospitals to more accurately describe and report the services provided during the actual planning process.

We urge CMS to refrain from treating different forms of SRS (i.e. cobalt vs. linear accelerator-based) differently by "bundling" treatment planning and treatment for cobalt-based systems and disaggregating these services for linear accelerator-based systems. The processes of treatment planning and treatment administration are clinically and conceptually distinct, and distinct resources are used for each. These services are included in separate subsections of the CPT and coding conventions for each are well established. We believe that "bundling" treatment planning and treatment administration for one SRS modality while "unbundling" it for another is potentially confusing and counterproductive.

IV. Summary of Recommendations

- Make G0339 image-guided robotic stereotactic radiosurgery a permanent code at the current APC 1528 rate for all treatments.
- Eliminate G0340 at APC 1525 and use G0339 at the current APC 1528 payment rate for all treatments.
- Eliminate all SRS/SRT treatment planning "G" codes and authorize hospitals to use the available CPT codes to accurately report the service provided during the treatment planning process for both cobalt and linear accelerator based SRS/SRT.

We appreciate your consideration of our comments.

Sincerely,

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Submitter : Mrs. Sandra Hazelwood **Date:** 09/15/2005

Organization : Caritas Wound Healing Center

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

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Submitter : Mrs. Pam Person **Date: 09/15/2005**

Organization : Caritas Medical Center

Category : Nurse

Issue Areas/Comments

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Submitter : Ms. Jacque Jenkins **Date:** 09/15/2005

Organization : Caritas Medical Center

Category : Nurse

Issue Areas/Comments

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Submitter : Mrs. Lisha Moore **Date:** 09/15/2005

Organization : Caritas Wound Healing Center

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

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Submitter : Dr. Bert Sparrow **Date:** 09/15/2005

Organization : Caritas Wound Healing Center

Category : Physician

Issue Areas/Comments

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Submitter :

Date: 09/15/2005

Organization : **Louisiana Association for Ambulatory Healthcare**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

Comment to CMS 1501-P 2006 Changes to Hospital Outpatient Payment Rates

CMS-1501-P-479-Attach-1.DOC

LOUISIANA ASSOCIATION FOR AMBULATORY HEALTHCARE
619 North Main Street
Jennings, LA 70546
WWW.LAAH.ORG

Department of Health and Human Services
Attention: CMS-1501-P 2006 OPPS PROPOSED RULE
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Date: September 13, 2005

Re: Comment to CMS-1501-P Changes to the Hospital Outpatient Prospective Payment System and calendar year 2006 Payment Rates

The Louisiana Association for Ambulatory Healthcare, an Association made up of Outpatient Mental Health Service Providers, offers the following comments to the 2006 Proposed Changes to the Hospital Outpatient Prospective Payment System.

The proposed rule referenced above continues to place extreme hardship on providers of Partial Hospitalization Programs. The rate set for 2006 once again falls below the actual cost of providing such services. In addition, it again unfairly discriminates against rural providers.

The rate for 2006 results in a net payment of 162.91 per day for rural Louisiana providers up to 180.90 per day in New Orleans. These rates are insufficient to cover the cost of caring for an acutely ill person with mental illness. The current standards for Partial Hospitalization Programs exceed requirements for 24-hour inpatient psychiatric facilities. They require extensive amounts of professional services, inclusive of nursing, therapy, ancillary services and psychiatry.

Over the past several years, programs in this State have been struggling to survive and continue to provide quality mental health services. Many providers have given up and shut down operations all together. Other Providers, such as Hospitals, only offer Outpatient Psychiatric Services (IOP). We ask that you consider the following information when preparing the final rule.

PAYMENT FOR PARTIAL HOSPITALIZATION VERSUS OUTPATIENT

The Payment for Partial Hospitalization Services includes a full program, inclusive of Nursing Staff, Psychiatrists, Medical Doctors, Psychologists, Masters Prepared Therapists, Chemical Dependency Counselors, Activity Therapists and Occupational Therapists. All therapies provided are included in the one daily rate for APC 033.

In contrast, Outpatient Hospital Psychiatric Services do not require a multidisciplinary team, no requirements for nursing staff and may consist of one Psychiatrist and one Therapist. In addition, the criteria for admission for patients treated at this level are much less than for PHP, resulting in a much lower patient acuity. For example, a Masters Level therapist provides a patient in this setting with one Family Therapy Session (APC 324 = $124.60), one Individual Therapy session (APC 323= $96.30) in a day and one Group Therapy Session (APC 325 = $78.27). Those three services have an allowable Medicare Payment of $299.17.

We clearly believe the rates for PHP should be adequately set to reimburse providers appropriate for the setting and level of care. Partial Hospitalization Programs should be reimbursed at a minimum, the average payment rates set for Psychiatric Outpatient Services. For example, based on CMS Payment rates in an outpatient setting, a minimal day of treatment in a Partial Hospital Setting would result in a payment of 331.11 per day. That is for 3 Group Therapy Sessions (APC 324) and one Individual Therapy Session (APC 323).

We ask the rates be set for PHP at a minimum of 331.11 per day.

NEED TO ADDRESS RURAL PROVIDERS

Over the past several years, CMS has made great gains in taking into account the special needs of rural providers. Congress has provided relief in many forms to ensure adequate healthcare in rural areas. We believe that Mental Health should be no exceptions.

For many of our providers, they are the only source for mental health treatment in the rural communities where they operate. As with other types of rural health providers, they are truly struggling to survive. The cost of providing services in rural areas generally runs higher per patient than in urban areas. This is due to several factors. For one, the struggle to get qualified staff in remote areas requires rural providers to pay higher wages to encourage people to commute. Most of these rural areas have no psychiatrists, no psychologists and few if any therapists. This results in constant recruitment and retention issues. In addition, unlike urban providers, the volume of clients served is much less.

We ask that CMS make provisions allowing for assistance to rural providers. We ask that the provisions given to Rural Hospital Outpatient Departments get passed along to Rural Community Mental Health Centers.

As an Association dedicated to ensuring access and quality of mental health services in the State of Louisiana, we ask you to consider our comments.

Thanks you,

Tehjan Martin RN,C
President - LAAH

Submitter : **Dr. Bruce Massau** **Date: 09/15/2005**

Organization : **Pain Management Consortium of Ohio**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-480-Attach-1.DOC

Pain Management
Consortium of Ohio, Inc.

Bruce A. Massau, D.O.
Diplomate of The American Academy of Pain Management

September 15, 2005

Via Electronic Submission: http://www.cms.hhs.gov/regulations/ecomments

Centers for Medicare & Medicaid Services
Department of Health & Human Services
PO Box 8016
Baltimore, MD 21244-8018

Attention: CMS-1501-P
Proposed Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2006 for Pass-Through Payment

To Whom It May Concern:

The Pain Management Consortium of Ohio welcomes the opportunity to comment on the proposed changes to the hospital outpatient rule which in our case modifies criterion for device eligibility for pass-through payment and presents an opportunity for rechargeable neurostimulators.

The product specifically that would impact our hospital is Restore, a rechargeable neurostimulator, and on August 1, 2005 CMS approved Medtronic's application for a "New Tech DRG Add-On Payment" in an inpatient setting and currently evaluating application for pass-through payment in an outpatient setting.

It is our understanding that Restore meets all of the required criteria to establish a new category for pass-through payment. Rechargeable neurostimulators in general meet the two tests CMS proposed in order to determine eligibility for the new category as rechargeable neurostimulators and radio frequency neurostimulators are distinctly different technologies.

Rechargeable neurostimulators contain an internal power source that is rechargeable whereas radio frequency requires an external power source that is not rechargeable and the therapy ceases immediately when the transmitter is removed from the implant site and has low patient compliance (i.e., skin breakdown).

1492 E. Broad Street, Suite 1203 • Columbus, Ohio 43205 • (614) 252-1500 • Fax (614) 252-1688

September 15, 2005
Attn: CMS-1501-P

Restore has shown substantial clinical improvement in patients with high patient compliance due to the ability to provide 24/7 therapy and recharging is in only required for a short period every 3-6 weeks. It provides those patients requiring high energy stimulation more treatment options and reduction in surgery due to battery replacement.

We urge CMS to consider Restore, a rechargeable neurostimulator, which meets all the criteria required for pass-through payment.

Sincerely,

Bruce A. Massau, DO
kas

Submitter : **Ms. Carolyn Aldige** **Date: 09/15/2005**

Organization : **Cancer Research and Prevention Foundation**

Category : **Consumer Group**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-481-Attach-1.DOC

CANCER RESEARCH AND PREVENTION FOUNDATION
www.preventcancer.org
CELEBRATING 20 Years OF PUTTING PREVENTION FIRST

Carolyn R. Aldigé
President and Founder

September 14, 2006

Center for Medicare and Medicaid Services

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS: 1501-P
Post Office Box 8016
Baltimore, MD 21244-9013

Re: Comments on proposed changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates

The Cancer Research and Prevention Foundation (CRPF) is a national non-profit organization with the mission of cancer prevention through research and education.

We are writing with respect to proposed regulations CMS 1501-P, specifically equitable adjustment, average sales price methodology and functional equivalence. Our primary interest in contacting you is to comment on your proposed revisions and how to ensure that treatment decisions remain squarely in the hands of the physician and patient, and are based on clinical and patient considerations, not on economics.

The proposed regulations indicate that CMS plans to discontinue applying an equitable adjustment to the payment rate for a drug, which CMS has used for the past several years. The agency indicates that its proposed move to use of the average sales price (ASP) methodology for setting OPPS rates for drugs renders such an adjustment unnecessary.

The Cancer Research and Prevention Foundation supports CMS's proposal on this issue. In our opinion, if OPPS payment rates for separately payable drugs are established based on the same methodology, there is no need to continue to impose the equitable adjustment that has been made over the past few years. Because there are numerous products payed under OPPS that compete with each other, and using an ASP methodology to set the rate for each by reference to its own pricing information levels would increase the likelihood that physicians and health care providers would choose the most appropriate treatment based on clinical and patient considerations.

In addition, we believe that use of ASP +6% to set the payment rates for all separately payable drugs under OPPS properly promotes parity in rate setting across sites of service. This also promotes the use of clinical and patient considerations, rather than financial incentives, in determining the appropriate site of service for Medicare beneficiaries. Accordingly, we ask that CMS finalize its proposal not to apply an equitable adjustment so that patient-centered considerations will always drive treatment decision.

The Cancer Research and Prevention Foundation is pleased that CMS has indicated movement away from equitable adjustment and towards ASP methodology, to permit market forces to determine the appropriate payment for drugs and biologics.

And in treatment for cancer and related side effects, functional equivalence is not a concept or practice that is in the best interest of the patient or their physician. We are pleased to see CMS moving away from this reimbursement concept and back towards the interest of the cancer patient. For example, CRPF supports the agency's proposal to "permit market forces to determine the appropriate payment" for Aranesp (darbepoetin alfa) and Procrit (epoetin alfa), two biological products that CMS previously has linked using its "equitable adjustment" authority (70 Fed. Reg. at 42727). In order to promote appropriate patient and physician choice in making healthcare decisions and to allow a market-oriented, ASP-based payment system to work as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) intended, CMS should permit the system to function without arbitrary government interference. We urge CMS to implement this proposal in the final rule.

Thank you for your review and consideration of our comments.

Sincerely,

Carolyn Aldigé

Carolyn R. Aldigé
President and Founder

Submitter : Mrs. Tracy Warner **Date:** 09/15/2005

Organization : Iowa Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachments.

CMS-1501-P-482-Attach-1.DOC

IOWA HOSPITAL ASSOCIATION

September 15, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Ref: [CMS-1501-P] Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates (70 *Federal Register* 42674), July 25, 2005.

Dear Dr. McClellan:

On behalf of the 43 Iowa hospitals currently subject to the Medicare outpatient prospective payment system (PPS), the Iowa Hospital Association (IHA) appreciates the opportunity to comment on the proposed rule which sets forth polices and payment rates for hospital outpatient services, as published in the July 25, 2005 *Federal Register.*

Since 1995, outpatient visits to Iowa hospitals have increased over 3.4 million, or 54 percent, with a 3.1 percent growth between 2003 and 2004. Outpatient surgeries represent over 75 percent of all surgeries performed in rural hospitals, a number that increases to almost 82 percent in rural areas. Outpatient revenue continues to rise in importance to Iowa hospitals, ranging from 45 percent of the patient revenue in urban hospitals to up to over 60 percent in rural hospitals. And outpatient visits to Iowa hospitals are cost-efficient, at an average charge per visit of $363, compared to the national average of $551 per visit. These statistics demonstrate how dramatically the Medicare outpatient payment system affects Iowa hospitals and the delivery of outpatient care in the state of Iowa where over 15% of the population is covered by the Medicare program. Consistent with comments filed by the Association in preparation of the implementation of the outpatient PPS in August 2000 and in response to proposed updates to the system for the last five years, IHA strongly encourages the Centers for Medicare & Medicaid Services (CMS) to seriously consider the impact of the annual changes in the outpatient PPS on the Medicare beneficiary's ability to access quality health care services, particularly in rural Iowa where there is a heavy dependence on outpatient services.

Given the fact that the outpatient PPS is under-funded, paying only 87 cents for every dollar of hospital care provided to Medicare beneficiaries, **CMS must consider the adequacy of the outpatient payment rates**. As evidenced by the -9.2% 2003 outpatient Medicare margins for Iowa hospitals, the outpatient PPS rates are set substantially below the costs hospitals incur in caring for Medicare beneficiaries, a fact that must be seriously considered before CMS alters payment levels and finalizes changes to various outpatient PPS policies. The variation of the ambulatory payment classification (APC) rates since the system was implemented has made it extremely difficult for hospitals to verify the accuracy of the rate setting and it limits their ability to respond to the incentives of a PPS with the appropriate planning and budgeting.

100 EAST GRAND DES MOINES, IOWA 50309-1835 515.288.1955 FAX 515.283.9366
www.ihaonline.org

In addition to the Association's comments regarding the payment levels and associated policy changes, IHA would like to offer the following comments regarding various aspects of the proposed rule.

Partial Hospitalization

IHA opposes any proposed reduction in partial hospitalization program (PHP) payments. As the proposed rule states, the median per diem cost for hospital-based PHPs has remained relatively constant, while the median per diem cost for community mental health centers (CMHC) has greatly exceeded the cost for hospital-based PHPs and has fluctuated significantly. Payment for hospital-based PHPs should not be penalized based on the fluctuation in cost data of CMHCs. Rather, hospitals should be rewarded for efficiently providing PHP services and incentives should be established based upon patient outcomes. CMS should be a purchaser of value and recognize the value of the PHP in keeping Medicare beneficiaries out of the more costly inpatient psychiatric setting.

Iowa hospitals are experiencing a severe shortage of psychiatrists and other mental health professionals. The state's 148 private practice psychiatrists work in 30 counties, leaving 69 counties with no psychiatric coverage; and Iowa ranks 47th in the nation in the number of psychiatrists per resident, according to the Department of Health and Human Services. This figure fails to account for the number of psychiatrists who will no longer treat patients in inpatient hospital units. For every 100,000 Iowans, there are only 6.6 practicing psychiatrists, worse than in all but three other states: Idaho, Nevada, and Mississippi. Most psychiatrists are clustered in urban areas, out of reach for rural Iowans who often lack access and resources to transportation.

As a result, hospitals are unable to staff all the licensed inpatient psychiatric beds. Further, the state-run and operated mental health institutes (MHIs) have closed 51 percent of its inpatient beds over the past 17 years. Waiting lists are in place at the four MHIs, and 135B hospital licensed psychiatric beds are often at capacity due to the shortage of MHI beds. It is because of the lack of psychiatrists and access to inpatient care that CMS should recognize the importance of the PHP services provided in the hospital setting as it is a valuable alternative to inpatient care that is often not available.

Many hospitals have closed or limited the number of patients they can accept. If payment for PHP services provided in the hospital setting is reduced, access to this benefit will be jeopardized as hospitals cannot continue to absorb the cost of providing these services. Further, if payment is decreased and more inpatient units are closed, Medicare beneficiaries will have difficulty accessing the necessary psychiatric care at the appropriate time in the most appropriate setting. The availability of proactive outpatient care is imperative to Medicare beneficiaries and to the Medicare program as it results in less frequent, more costly, emergency room visits and inpatient hospitalizations that require longer periods for recovery. Any reduction in the PHP payment will result in less access to PHP services, and further exacerbate access to necessary psychiatric services.

Rather than reduce the PHP rates 15% as proposed, IHA recommends CMS freeze the payments for PHP services at the current level in order to stabilize payment and preserve access to necessary care for beneficiary while CMS studies the fluctuations in the CMHC cost data.

Rural Hospital Adjustment

IHA has been a consistent supporter of the Congressionally-mandated protection to provide temporary transitional payments to rural hospitals and rural sole community hospitals (SCHs) as a mechanism to allow the reimbursement levels under the outpatient PPS to stabilize. IHA receives data from the fiscal intermediary each month on the amount of transitional outpatient payments (TOPs) made to Iowa hospitals. The Association's analysis of this information shows that 21 Iowa hospitals were still receiving TOPs in August 2005, the latest data available, with total TOPs to Iowa hospitals since the provision was made available in September 2000 exceeding $59 million. This data indicates that hospitals in Iowa, and likely other states, are relying on transitional payments to hold the system together, and is cause for extreme concern given the expiration of the temporary payments at the end of 2005. IHA will work to extend this protection permanently to ensure the continued viability of these vulnerable facilities in the rural areas they

serve.

Although the proposed rule presents the findings of a Congressionally-mandated study to determine if rural hospital outpatient costs exceed urban hospital outpatient costs, and proposes a 6.6 percent payment increase for rural sole community hospitals (SCHs), IHA is concerned with the reporting of the outcomes of the study for rural hospitals with less than 100 beds. The lack of detail available in Table 6 of the rule regarding non-SCHs with fewer than 100 beds does not allow the public to fully evaluate the results of CMS' study. In particular, IHA data indicates that the hospitals most in need of additional outpatient payments, based on the amount of transitional payments received since September 2000, are those small, rural hospitals without any additional Medicare payment designation such as SCH status. For example, two Iowa hospitals, with 81 and 68 beds, have each received over $700,000 in total TOPs payments. (see attached excel spreadsheet analysis.) **IHA recommends CMS provide additional detail regarding its study and results for hospitals with less than 100 beds to support its proposal to adjust the rates for SCHs only and not other small, rural hospitals.**

In addition, IHA requests clarification on the SCHs that will be eligible for this adjustment. Will the adjustment apply to those SCHs located in rural areas but that are reclassified for wage index purposes to an urban area?

Outlier Payments
IHA supports the inclusion of an outlier payment within the outpatient PPS to provide for an additional payment for high cost cases but has concerns regarding CMS' proposed change to reduce the amount of available outlier funds from two to one percent, and the increase in the fixed loss threshold to $1575.

IHA recommends CMS provide additional detail in the final rule to support its proposal to increase the outlier threshold by $400 over the CY 2005, as well as data on the actual outlier payments made in 2005. This analysis will help determine if the proposal to reduce the percent of outlier funds is justified, given the past history of total outlier payments.

E/M Services
Since the implementation of the outpatient PPS, CMS has directed hospitals to create and utilize an internal set of guidelines for determining the appropriate CPT code selection associated with the level of service provided in hospital outpatient clinics and emergency department visits, even though these codes were originally developed to describe physician resources associated with such services. In the 2004 outpatient PPS proposed rule, CMS indicated it was considering proposed national guidelines recommended by an independent panel of experts.

After lack of address in both the 2004 and 2005 outpatient PPS rules, IHA is again disappointed that CMS has not moved forward with a recommendation for a proposed E/M model in 2006. The lack of standardization presents compliance issues for hospitals, and in addition, it adversely impacts CMS' ability to gather appropriate data for these services which impact the rate setting associated with services provided in the emergency department and hospital clinics. **IHA recommends CMS release a proposal on hospital coding of E/M services as soon as possible.**

Inpatient Procedures
CMS currently identifies certain procedures that are typically provided only in an inpatient setting and thus, are not payable under the outpatient PPS. In the 2005 rule, CMS is proposing to remove 25 codes from this list.

IHA continues to support a past recommendation from the APC Panel to eliminate the inpatient only list and encourages CMS to reevaluate the decision regarding its existence. Physicians, not hospitals, determine what procedures will be performed and in what location, depending on a patient's condition. If a physician's clinical decision-making process determines that a procedure can be performed safely in an outpatient setting and that particular service is on the inpatient only list, the hospital is

penalized, yet the physician reimbursement is unaffected. IHA recommends the inpatient only list be eliminated because payment policy is driving the location of where services are performed, rather than clinical decision-making.

Multiple Diagnostic Imaging Procedures

IHA opposes the implementation of a policy that will reduce payment when multiple imaging services within the same "family" of procedures are provided in the same session. Consistent with a recommendation from the Medicare Payment Advisory Commission (MedPAC), CMS proposes to make full payment for the highest paid imaging services but reduce reimbursement to 50 percent of the payment rate for each additional procedure within the same family performed during the same session.

IHA opposes this proposal on the basis that CMS has not performed sufficient analysis of hospital data to support its position. By its own admission, CMS states that outpatient PPS bills do not contain detailed information on hospital costs that are incurred in furnishing imaging procedures, so the agency used the Medicare Physician Fee Schedule (MPFS) methodology and data. However, CMS has failed to take into account the vast differences in how physician payment rates are determined versus the calculation of hospital rates based on facility costs. Further, since the analysis using hospital data has not taken place, CMS has not provided sufficient justification for its rationale to reduce the payment rate by 50 percent. Before CMS moves forward with this policy, the agency must conduct a more detailed analysis using hospital data, as well as provide more detail regarding the specifics, including a definition of the "same session".

Physician Oversight of Nonphysician Practioners

IHA supports CMS' proposal to remove physician oversight of nonphysician practioners providing care to critical access hospital (CAH) outpatients if state law allows independent practice authority. The state of Iowa grants independent practice authority to nonphysician practioners such as nurse practioners, clinical nurse specialists and physician assistants and Iowa's 73 CAHs rely heavily upon mid-levels to provide outpatient services. This change will allow the nonphysician practioners and physicians to focus on patient care with jeopardizing the safety and quality of care provided to Medicare beneficiaries, as evidenced in the studies cited in the proposed rule.

Once again, IHA appreciates the opportunity to provide comment on the proposed changes to the outpatient PPS for 2006 and encourages CMS to carefully evaluate the impact of its proposed policies by weighing decisions regarding appropriate payment levels with the need to provide continued access to high quality and cost-efficient outpatient services to Medicare beneficiaries in their local communities. Please contact me at 515/288-1955 with any questions regarding IHA's comments.

Sincerely,

Tracy Warner

Tracy Warner
Vice President, Finance Policy

cc: Iowa congressional delegation
Iowa hospitals

CMS-1501-P-483

Submitter : Dr. D. Jeffrey Demanes **Date:** 09/15/2005

Organization : American College of Radiation Oncology

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached letter from the American College of Radiation Oncology signed by Dr. D. Jeffrey Demanes (ACRO President) and Dr. Michael R. Kuettel (Chair, ACRO Economics Committee.) Thank you.

CMS-1501-P-483-Attach-1.PDF

American College of Radiation Oncology
5272 River Road • Suite 630 • Bethesda, MD 20816
(301) 718-6515 • FAX (301) 656-0989 • EMAIL acro@paimgmt.com

September 15, 2005

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Proposed Rule Hospital Outpatient Prospective Payment System for 2006 CMS-1501-P

Dear Dr. McClellan:

The American College of Radiation Oncology (ACRO) wishes to offer comments to the Centers for Medicare and Medicaid Services about the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule posted in the *Federal Register* on July 25, 2005.

We are very concerned about the reduced payment proposed for brachytherapy APC 312, 313, and 651. We understand that only a small percentage of services were sampled due to the rules for single claims analysis. Brachytherapy typically involves multiple services so single claims are not representative and it is apparent that the pseudo single claim approach and the exclusion list did not effectively mitigate the problem. The proposed reimbursement is dramatically reduced for the foundation CPT codes for prostate and other complex interstitial brachytherapy (CPT 77778) and intracavitary gynecological brachytherapy (CPT 57155). In addition, the proposed changes in the Medicare Physician Fee schedule for certain brachytherapy codes including 57155 (see separate communication to follow) by reducing office practice expense by minus 100% would effectively eliminate a venue for gynecological brachytherapy. It appears that non-representative and erroneous claims are having disproportionate impact on the reimbursement rates for these codes that CMS, as proposed in the recent notice. We believe that payment for this service is already at or below cost and further reductions will be severely detrimental to patient care.

CMS has used only 3 percent of all claims for APC 0651 and that does not seem representative to us. Study has shown that claims that had both the brachytherapy procedure and a brachytherapy source "C" code had median costs that were significantly higher than the average all single-procedure claims for the APC. We believe that a thorough analysis of brachytherapy would show that it is a complex process that requires resources in excess of the proposed reimbursement.

We realize that the agency has attempted to include multiple procedure claims data to calculate relative payment weights by using the "same date of service" and an expanded list of "bypass"

codes to provide more "pseudo" single claims. We believe, however, that changes in the current methodology must be used to gather accurate, complete, and representative cost data. A "device-dependent" APCs or some other solution may be necessary to ensure more appropriate and accurate payment rates for brachytherapy APCs. Furthermore that a study of the both the process and resources would show that the cost of providing this traditionally effective treatment to cancer patients in the hospital outpatient setting exceeds the proposed reimbursement. In our opinion the restrictive nature of the dataset and the incomplete listing of resources has resulted in significant reductions in payment. We recommend the following for your consideration:

1. Use only "correctly coded" claims for brachytherapy APCs 312, 313 and 651.

2. Apply a "dampening" adjustment to all device-related APCs to limit the reduction in payment from 2005 to 2006 rates, including APCs 312, 313 and 651.

3. Require mandatory hospital coding of appropriate brachytherapy source "C" codes for brachytherapy procedure APCs 312, 313 and 651.

4. Educate hospitals on the importance of accurate coding of devices, including brachytherapy sources.

5. Develop alternative methodologies to utilize single and multiple-procedure claims for determining median costs and setting HOPPS payment rates, including the use of the best external data available in constructing APC rates, including proprietary or confidential data, to determine median cost calculations.

6. Maintain CPT 57155 in APC 193 *Level V Female Reproductive Procedures.* Further, we request that all changes to APC assignments be listed in the preamble of future proposed and final rulemaking.

7. CMS work with the American College of Radiation Oncology (and other specialties as appropriate) to study the breadth of services and resources needed to provide brachytherapy

Methodology

We noticed that all other radiation oncology codes have increased with the exception brachytherapy codes in APCs 312, 313 and 651. We are concerned that the reductions are based in part upon inaccurate hospital coding of brachytherapy source device "C" codes, elimination of multiple-procedure claims used to determine relative weights, and utilization of "incorrectly" coded brachytherapy claims to determine payment rates. There is across the board reduction in payment rates for the calendar 2006 compared to 2005: (312) –6.6%, (313) – 3.5%, and (651) – 42.3%. We believe the single claims and that the pseudo single claims data do not accurately reflect the cost of providing the service because they are both atypical and too few in number to be representative. They represent 2.8% for code 651 (total 11,963 claims) and 41.2% for code 312 (total 882 claims only). *The typical brachytherapy service is a multiple claims process.* There are often associated codes in the 777xx and other code series such as 55859, 31543, 43241, 57155, 58346 and others. In addition the equipment, supplies, and personnel required for

brachytherapy often cross medical specialties and departments within the hospital system. We also believe that correct coding is both more complex and less likely to be complete and consistent, especially with the regular changes from year to year.

We urge that CMS modify the data analysis method for brachytherapy to take into account that it is fundamentally a multiple procedure and often multi-disciplinary process.

We also recommend that external data such as proprietary or confidential data should be used determine median cost calculations if payment rates are based upon a small percentage of claims reviewed. The criteria for such submissions should be such that meaningful data can be included.

Various analyses have shown that correctly coded claims tend to result in median costs that are significantly higher than the CMS calculations based upon limited data. We believe it is the intention of the agency to correctly match cost and reimbursement for each type of service. Since brachytherapy is applicable to a broad range of cancer types it would most reasonably be coded with many categories and be site specific much like surgery and other procedure type services. Lumping all brachytherapy into few categories reflects a limited understanding of the diversity of the service and the resources necessary for its delivery. The concern is that the complexity is so variable that a "one size fits all" approach does not adequately address the cost of providing the service. Unlike some other services there is a particularly great variability between facilities in the type of brachytherapy services offered. Using a typical or average case approach therefore undermines the financial viability of centers that provide particularly complex brachytherapy.

Given these complexities and the frequent change in the system in recent years it is not surprising that hospitals find it hard to correctly code claims and that the agency is having difficulty in finding a balanced and stable means of providing reimbursement to the facilities. Within the confines of the current system we would suggest the following:

1. Claims have both the brachytherapy procedure and a brachytherapy source "C" code
2. A coding screen, similar to the screens CMS applied to "device-dependent" APCs be used to ensure more appropriate and accurate payment rates for brachytherapy APCs.
3. CMS use only "correctly coded" claims to determine brachytherapy payment rates and that multiple claims be analyzed.
4. If data is insufficient then external cost information should be applied.

The following table correlates the type of radioactive material to the existing APCs for brachytherapy.

APC	CPT Codes	Brachytherapy Device "C" Codes
312 Radioelement Applications	77761, 77762, 77763, 77776, or 77777	C1716, C1718, C1719, C1720, C2616, C2632, or C 2633
313 Brachytherapy	77781, 77782, 77783, 77784, or 77779	C1717 only
651 Complex Interstitial Radiation Source Application	77778	C1716, C1718, C1719, C1720, C2616, C2632, or C 2633

We suggest that CMS review the 2004 claims data used to package appropriate costs into Brachytherapy APCs 312, 313 and 651 to ensure that the reasonable cost of the brachytherapy source(s) was included on each hospital claim. We request that CMS select the claims that accurately reflect the source and device costs and delete the claims that do not, and revise the final payment rate for 2006 to reflect the appropriate cost of the brachytherapy procedure(s).

CMS should issue a Medicare Program Transmittal instructing providers to report the cost of the brachytherapy source(s) on all brachytherapy procedure claims. We request that CMS also instruct providers to report all brachytherapy procedures by date of service.

CPT 77778 Interstitial Radiation Source Application

APC 651 includes one CPT code 77778 *Interstitial Radiation Source Application; Complex.* This interstitial brachytherapy procedure is used to code most often but not exclusively for prostate brachytherapy. The reduction in payment to the facility for this service is dramatic. We believe it brings reimbursement to levels below the median cost of providing the service.

There are some practical limits on changes in cost per year for a service and these should be reflected in the HOPPS. It is not conceivable that costs for complex interstitial brachytherapy would change in one year by 42% (minus). For some reason, CMS did not apply its policy of stabilizing all device-related APC rates by protecting against such large cuts to APCs. For the last several years, CMS established a "dampening" adjustment to virtually all APCs (except "New Technology" APCs). These adjustments were created to limit the impact of payment reductions from year to year. A dramatic payment reduction of more 42.3% for APC 651 will cause hospitals to negatively consider their ability to provide this service. Further considerable payment instability makes it impossible to plan and develop quality brachytherapy programs.

We recommend therefore that CMS apply the "dampening" adjustment to all device-related APCs, including APC 651, and limit the reduction in payment from 2005 to 2006 rates.

In 2004, there were 11,963 claims that contained CPT code 77778; however, CMS based the 2006 proposed payment on just 342 claims or approximately only 2.8% of outpatient claims. If CMS had used claims that contained CPT 77778 and at least one brachytherapy device "C" code, the median cost increases by approximately 18% to $864.54. In past years, CMS has used only "correctly coded" claims to determine payment rates. A claim for brachytherapy without a C-code would imply that brachytherapy was not delivered or that it was incorrectly coded.

We request that CMS review the 2004 claims data for APC 651 *Complex Interstitial Radiation Source Application* to ensure that the reasonable costs of brachytherapy sources are included on each hospital claim that contains CPT procedure code 77778.

If the 2006 median for APC 651 results in a 15% or greater reduction than the current 2005 payment, we request that CMS apply the "device-dependent" or similar adjustment factor to limit the decrease to 85 percent of the CY 2005 median.

CPT 57155 Insertion of Uterine Tandems and/or Vaginal Ovoids for Brachytherapy

CMS proposes to move CPT 57155 *Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy* from APC 193 *Level V Female Reproductive Procedures* to APC 192 *Level IV Female Reproductive Procedures*. The current payment for CPT 57155 is $758.17 and decreases by 66.4% in 2006 with assignment in APC 192 with a 2006 proposed payment of $255.66. We are very concerned about this level of reduction. This code is relatively new and unfamiliar to hospitals. We are also aware that many of our members did not understand how to use the code properly and that the billing departments were confused. There are at least two circumstances where code 57155 may be applied in the hospital outpatient setting: 1) operating room with anesthesia or 2) brachytherapy suite with conscious sedation and local anesthesia. In both cases considerable resources of personnel, supplies, and equipment are required. The most common approach involves placement of an intrauterine brachytherapy device (cost $55) that must be sutured to the cervix. The purpose of the device is to permit safe and correct placement of the tandem (commonly in a series of brachytherapy sessions.) Surgical equipment for vaginal surgery, scrub technologist, circulating nurse, bladder catheter, intravenous tubing and fluids, gauze pads, vaginal packing, suction, cervical markers, and various means to achieve hemostasis are required. The tandem and ovoid or similar applicator used for brachytherapy must also then be inserted under anesthesia or conscious sedation. The tandem and ovoids may be reusable (costs in the range of $15,000) or disposable (costs.) It is apparent to us that the proposed payment rate does not cover the cost of providing the service and the data used in the calculation are suspect.

We recommends that CMS maintain CPT 57155 in APC 193 *Level V Female Reproductive Procedures.* Further study of the costs of this procedure are required to set accurate reimbursement and we would be interested in working with CMS to that end.

Summary

The major changes to brachytherapy reimbursement are of concern to the American College of Radiation Oncology. The diversity of brachytherapy services and the differences in the type and complexity of procedures performed within and between facilities is noteworthy. The advanced technology of permanent seeds and high dose rate mean that much of brachytherapy can now be done on an outpatient basis. While inpatient service may decrease there will necessarily be some compensatory increase in costs in the outpatient setting. We believe that the decrease in reimbursement across the board for brachytherapy related APCs (312,313,651) are not well correlated with the true cost of providing the service and that such reductions will negatively impact brachytherapy health care deliver.

Further one of the foundation codes 57155 (APC 193) for gynecological brachytherapy applicator placement has been drastically reduced (by transfer to a lower APC category). These brachytherapy services are intrinsically linked in the step-by-step process (from applicator placement, to imaging, to dose calculation, and finally to radiation source delivery.) A change in

one impacts the entire service series, making single claim analysis inadequate and misleading. We also recognize the difficulties of calculating correct payment rates for such a complex process and hope that some solution to the methodology can be found.

We appreciate the opportunity to bring our views to the attention of the agency, and we would like to offer our assistance the agency in the study of the costs associated with of providing brachytherapy services.

Respectfully submitted,

D. Jeffrey Demanes, MD, FACRO
President

Michael R. Kuettel, MD, PhD, FACRO
Chair, ACRO Economics Committee

Submitter : Mrs. Tracy Warner

Organization : Iowa Hospital Association

Category : Health Care Provider/Association

Date: 09/15/2005

Issue Areas/Comments

GENERAL

GENERAL

See excel spreadsheet attachment that accompanies the comment letter from the Iowa Hospital Association. I was unsuccessful in attaching it with the comment letter.

CMS-1501-P-485

Submitter : Ms. sajini thomas **Date:** 09/15/2005

Organization : wright medical technology

Category : Device Industry

Issue Areas/Comments

GENERAL

GENERAL

"See Attachment"

CMS-1501-P-485-Attach-1.PDF

September 16, 2005

VIA ELECTRONIC TRANSMISSION
Mark McClellan, M.D. Ph. D
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1501–P
P.O. Box 8016
Baltimore, MD 21244–8018

Re: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule
CMS-1501-P
"Pass Through"

Dear Dr. McClellan

Wright Medical Technology, Inc. welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates; Proposed Rule"*, 42 CFR Parts 419 and 485 (July 25, 2005)("NPRM"). Wright Medical Technology develops and manufactures orthopedic tissue biologics as well as medical devices. Our GRAFTJACKET® line tissue biologics are covered as incident-to drugs and biologics under the Part B Medicare Program. These products include GRAFTJACKET® Regenerative Tissue Matrix—Ulcer Repair and GRAFTJACKET® XPRESS Flowable Soft Tissue Scaffold, which are used in the treatment of complex wounds.

As explained more fully below, Wright recommends:

- CMS finalize the proposal to continue payment for Graftjacket Matrix (C9221) and Graftjacket Soft Tissue Scaffold (C9222) as pass-through biologics in 2006, the second year of their pass-through status.
- CMS confirm the payment amount for code C9221. We were not able to confirm the payment amount included in the Proposed Rule.

1. CMS should finalize the proposal to continue pass-through payment for Graftjacket Matrix (C9221) and Graftjacket Soft Tissue Scaffold (C9222)

In the NPRM, CMS has proposed to continue the pass-through status for Graftjacket Matrix (code C9221 "Acellular dermal tissue matrix per 16 cm2") and Graftjacket Soft Tissue Scaffold (code C9222 "Decellularized soft-tissue scaffold, per 1 cc") under the OPPS during 2006. Codes C9221

and C9222 were issued effective January 1, 2005. Therefore, it is appropriate to maintain the pass-through status for these products through the end of 2006.[1]

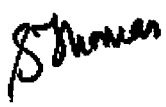
2. Please confirm the payment amount for Graftjacket Matrix C9221.

In the NPRM, CMS has proposed a payment amount of $1,234.36 for code C9221.[2] This reflects an ASP plus 6-percent payment of $1,211.87.[3] As the descriptor for code C9221 is per 16 cm^2, this would yield an ASP plus 6-percent payment of $75.74 per cm^2. We cannot confirm this payment amount. We believe it was based upon ASP information for Graftjacket Matrix for 4Q2004, submitted by Wright Medical Technology in January 2005, however, the amount differs slightly from what we would calculate.[4] Therefore, we would request that CMS confirm the calculation for the Final Rule and subsequent quarters in 2006.

* * * *

We appreciate the opportunity to submit comments on the above-captioned rule. If you have any questions or would like additional information, please contact Sajini Thomas at 901.606.6224.

Sincerely yours,



Sajini Thomas
Director of Reimbursement Services

[1] Soc. Sec. Act 1833(t)(6)(B)(iii).
[2] 70 Fed. Reg. 50680,50836 (Aug. 26, 2005).
[3] Addendum C
<http://www.cms.hhs.gov/regulations/hopps/ama_agree_hosp_pps.asp?URL=/providers/hopps/2006p/AddenC_1501p.zipaddenc_1501p.xls>
[4] By our calculation, the ASP+6% payment amount based upon the 4Q2004 submission would be $76.418-per cm^2.

CMS-1501-P-486

Submitter : Dr. David Kloth **Date:** 09/15/2005

Organization : American Society of Interventional Pain Physicians

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-486-Attach-1.PDF

The Voice of Interventional Pain Management

Since 1998

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asipp@asipp.org

September 15, 2005

Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
CMS-1501-P
Post Office Box 8016
Baltimore, MD 21244-8018

File Code: CMS-1501-P

Dear Dr. McClellan:

On behalf of the **American Society of Interventional Pain Physicians** ("ASIPP"),[1] I want to thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") Notice of Proposed Rulemaking ("NPRM") regarding the Hospital Outpatient Prospective Payment System for 2006[2] as it pertains to Medicare payment for interventional pain procedures. ASIPP supports the proposal put forth by CMS to modify pass-through criteria for new technology add-on payments, especially as it relates to rechargeable implantable neurostimulators – a new technology to treat life-interfering chronic pain.

Criteria for Establishing New Pass-Through Device Categories - Existing Device Category Criterion

In the proposed rule, CMS states, "[o]ne of our criteria, as set forth in § 419.66(c)(1) of the regulations, to establish a new device category for pass-through payment, is that the devices that would populate the category not be described by any existing or previously existing category." ASIPP is pleased by this statement and would like to support the application made by manufacturers to create a new pass-through category for a rechargeable pulse generator neurostimulators, starting January 1, 2006.

ASIPP supports CMS in its decision to allow a device to qualify for new technology add-on payments in the hospital outpatient setting, if the technology provides a substantial clinical improvement for Medicare beneficiaries and that it is not described by any existing or previously existing category. The implantable pulse generator (IPG) neurostimulator meets both tests. As part of our request for a new technology add-on payment for IPGs, we are also requesting a revision of the previously existing category for implantable neurostimulator generators to clarify that it describes *non-rechargeable* implantable neurostimulator generators.

Implantable pulse generator neurostimulators represents a major medical advance in medical technology that has important technological differences versus existing

(More)

non-rechargeable IPG's and external RF-transmitter systems. Rechargeable neurostimulators provide relief for patients suffering with chronic pain. Neurostimulation has been shown to be better than other pain relief modalities for certain patients. For some patients, it is the only treatment that provides them with some pain relief, without which their ability to perform daily activities and to be productive is dramatically altered. Unless this issue is addressed, this technology may be available only to non-Medicare beneficiaries.

Because surgery is involved, many patients view this treatment as a treatment of last resort. Those who have received the IPG, benefit from targeted, effective pain relief. Advanced programming capability enables the physician to better capture pain, and increases the physician's ability to make adjustments to output, specifically with amp and frequency levels.

Implantable pulse generator neurostimulators also provide a substantial clinical improvement for Medicare patients over currently available technologies because they greatly reduce the need for battery replacement surgeries and reduce device-related complications and hospitalizations compared to non-rechargeable units and RF-transmitter systems, permitting physicians to use higher levels of energy when medically indicated and improve device programmability. Fewer surgeries over a patient's lifetime, means less risk of infection to the patient and less risk of co-morbidities.

The previously existing device category for implantable neurostimulator generators does not appropriately describe rechargeable IPG technology. The previously existing category descriptor is overly broad and it was never intended to describe rechargeable IPG technology that did not exist at the time the category was created.

Neurostimulation has been shown to provide improved pain control over other modalities for certain patients. If hospitals refuse to allow these procedures for Medicare patients, they could lose access to the only effective pain treatment available. We cannot overemphasize that for some patients, neurostimulation is the only treatment that provides pain relief – without which their ability to perform daily activities and to be productive would be dramatically altered.

ASIPP would like to thank CMS for its recent approval of new technology add-on payments for rechargeable neurostimulators in the hospital inpatient setting under Medicare for services beginning October 1, 2005. We appreciate the Agency's recognition that rechargeable neurostimulators are significantly different than predecessor devices and that the technology is a substantial clinical improvement for patients. Obviously CMS has decided this is an important technology and it would only be consistent to apply the same changes to the hospital outpatient setting.

Base Payment – APC 0222

APC 0222 (CPTs 63685 and 64590) contains payment for the implantation of a neurostimulator generator. CMS has proposed a $1,792 – or 14 percent payment reduction for this APC in FY

(MORE)

2006, which would reduce the payment from $12,373 to $10,581. Past experience has shown the members of ASIPP that hospitals are very reluctant to permit physicians to perform procedures where the facility loses money, particularly procedures that involve costly technology. ASIPP is very concerned that hospitals will not be able to absorb the $1,792 reduction in payment for non-rechargeable neurostimulator placement and will begin to reconsider allowing physician to perform this procedure. This situation will cause further complications in trying to give Medicare beneficiaries access to new rechargeable technology. Certainly hospitals will refuse to allow the implantation of rechargeable units, if they already are experiencing a financial burden related to the less costly, non-rechargeable technology. Consequently, it is critical that rechargeable neurostimulator technology be given strong consideration for pass-through status.

We appreciate the opportunity to comment on the proposed rule and recommend that CMS adopt its proposal to modify criteria for establishing new device pass-through categories, consider a new pass-through category for rechargeable technology, and that CMS revisit the change in the base payment for neurostimulator placement, APC 0222.

If you have any questions, please feel free to contact me.

Sincerely,

David S. Kloth, M.D.
President, ASIPP

[1] ASIPP is a not-for-profit professional organization comprised of nearly 3,000 interventional pain physicians who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain.
[1] 70 Fed. Reg. 42674 (July 25, 2005).

Submitter : Mrs. Catherine Meeter **Date:** 09/15/2005

Organization : Sutter Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

Re: Section XIII, A. Proposed Indicator Assignments. CMS states 'the payment status indicators (SIs) that we assign to HCPCS codes and APCs under the OPPS play an important role in determining payment for services under the OPPS because they indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code.' Sutter Health has a concern about the current status indicator assigned to CPT codes 0062T and 0063T. These are both listed with a status indicator of T. Research for all Carriers and FIs shows that this is non-covered for Medicare beneficiaries. Why are these coes not listed with a SI that indicates these are not payable by Medicare and should CMS mark these as non-payable for 2006? How would hospitals know to place an edit on these codes if the codes are assigned by our medical records department to charges for timed surgical procedure charges? Please consider marking these codes with a SI that indicates these are not covered by the Medicare program.

Submitter : Mr. Thomas Gosrich **Date:** 09/15/2005

Organization : CVPH Medical Center

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I write to object to the proposal for the OPPS Rates. In support of the objection I would like to mention the following important considerations.

- A June 30, 2005, report on hospital outpatient department pharmacy handling costs prepared by the Medicare Payment Advisory Commission (MedPAC) noted that "Handling Costs" are "not insignificant" and that they "made up 26 percent to 28 percent of pharmacy departments' direct costs." I disagree with CMS's decision instead of accepting MedPAC's analysis, to pay only an additional 2 percent of the ASP scaled for budget neutrality to cover the handling costs of these drugs."

- This reimbursement formula is inadequate to cover handling costs of drugs. Small hospitals, like ours, may be forced to limit or eliminate the treatment of patients in outpatient settings. The ramifications of instituting this formula will be disastrous. The places and processes of providing services will change - to the detriment of patients who will not receive treatment by their providers of choice. Inadequate reimbursement to hospital outpatient departments will impact the quality, safety and level of their services.

- I Support the proposal being made by the Association of Community Cancer Centers (ACCC) that CMS consider an allowance of 8% to cover pharmacy handling and overhead expenses for all drugs reimbursed under the hospital OPPS, in addition to ASP + 6% to cover the drug acquisition cost.

- Given the fact that CMS must collect hospital charge data for overhead costs for two years to determine if even the 8% rate is adequate and consider new reimbursement rates for these costs for payment in 2008, these 2 years may make the difference for many of our patients.

Submitter : Ms. Denise Garris **Date:** 09/15/2005

Organization : American College of Cardiology

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-489-Attach-1.DOC

P-489

Heart House
9111 Old Georgetown Rd.
Bethesda, MD 20814-1699
USA

(301) 897-5400
(800) 253-4636
Fax: (301) 897-9745
www.acc.org

September 16, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS 1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Dear Dr. McClellan:

The American College of Cardiology (ACC) is a 30,000 member non-profit professional medical society and teaching institution whose mission is to advocate for quality cardiovascular care—through education, research promotion, development and application of standards and guidelines—and to influence health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC is pleased to offer comments on the notice of proposed rulemaking entitled **Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates (CMS -1501-P)** published in the July 25, 2005 **Federal Register**. The College's objective in reviewing and commenting upon Medicare's proposed policies is to ensure that Medicare beneficiaries have access to high quality cardiovascular care. We believe that rational, fair provider payment policies are essential to ensuring that access.

APC Panel Recommendations for APCs 0107 and 0108

CMS proposes to set payment rates for APC 0107 (Implantation of Cardioverter Defibrillator) and APC 0108 (Insertion/Replacement/Repair of Cardioverter-Defibrillator Leads and Insertion of Cardioverter-Defibrillator) at 85% of the calendar year 2005 payment rates for these two APCs. If implemented, the proposed payment rates would represent a decrease of approximately 16% in the past two years. More significantly, the proposed payments would be inadequate to cover the cost of acquiring the ICD devices. The proposed inadequate payment rates reduce the likelihood that Medicare beneficiaries will receive ICD therapy in the most appropriate care setting.

The proposed rule outlines important deficiencies in the hospital outpatient charge data used to establish the median costs for APCs 0107 and 0108. During the August 17-18 meeting of the Advisory Panel on APC Groups, testimony from public presenters and comments from CMS staff underlined these concerns, noting doubts about the accuracy of hospital reporting of device costs for APCs 0107 and 0108. The Advisory Panel recommended that CMS establish the 2006 payment rates for APCs 0107 and 0108 at 100% of the 2005 payment rates, plus the 3.2% outpatient hospital update. In light of the ongoing questions about the accuracy of the charge data underlying median cost estimates, as well the documented inadequacy of the proposed payment levels, the ACC urges CMS to adopt the Advisory Panel's recommendation. In addition, we encourage CMS to continue efforts to improve the charge data used to establish median costs for APCs 0107 and 0108.

CT and CT Angiography

The ACC is concerned about payment levels and APC assignment for CT angiography (CTA). Significant modifications in coding for CTA procedures, along with the expansion of clinical practice over the past few years lead us to believe that CMS should reexamine its categorization of these procedures. We recommend that the issue of appropriate APC assignment for CTA services be placed on the agenda for the next meeting of the Advisory Panel on APC Groups.

In addition, the AMA CPT Panel recently approved eight new category III CPT codes for CTA. These codes will be implemented on January 1, 2006. We ask CMS to outline its plans for implementing the Category III CPT codes within HOPPS.

Appropriate Classification of Dipyridamole (J1245)

Nuclear cardiology procedures utilize three major pharmacological stress agents: adenosine (J0152 & C9223), dipyridamole (J1245) and dobutamine (J1250). Dobutamine is a low cost stress agent used for very specific clinical indications. However, the vast majority of cardiovascular patients undergoing pharmacological stress receive adenosine or dipyridamole. Currently, both adenosine and dipyridamole are classified with a K status indicator and are therefore paid separately in addition to the APC payment for the procedure.

CMS now proposes to bundle dipyridamole into the APC payment. The proposed rule states that the reported median cost is just under fifty dollars ($48.85). We understand that HOPPS sets a threshold of $50 for bundling payment for certain items into the APC payment for the associated procedure. The ACC is concerned, though, that eliminating separate payment for dipyridamole could limit access to this drug for patients who would benefit from its use. ACC recommends that CMS maintain a status indicator of K for J1245 dipyridamole so that a patient can receive the stress agent that is most appropriate for his or her clinical situation.

Multiple Diagnostic Imaging Procedures

CMS proposes to reduce payment under the hospital outpatient prospective payment system (HOPPS) for some multiple diagnostic imaging procedures provided during the same session. Specifically, CMS asserts that when multiple imaging procedures using the same modality are performed on contiguous body parts some clinical labor, supply, and equipment costs overlap. CMS therefore plans to reduce the APC payment for the second and any subsequent procedure within each of 11 families of imaging procedures by 50 percent. The proposed rule states that CMS based this decision on an analysis of the data used to establish the resource based practice expense relative value units under the Medicare Physician Fee Schedule (MPFS). CMS also notes that a similar multiple procedure payment reduction is in effect for surgical procedures under both HOPPS and MPFS.

The ACC believes that CMS has erred in assuming that the same percentage payment reduction that is applied to the APCs for multiple surgical procedures should be applied to APC payments for multiple diagnostic imaging services. APCs for surgical services include payment for the activities and resources required to care for the surgical patient before and after the surgical procedure, as well as during the procedure itself. For example, surgical APCs include the cost of pre-procedure nursing care, recovery room care, and blood products. These pre- and post-procedure activities and resources make up a significant portion of the overall costs associated with the surgical procedure. It may not be unreasonable, then, to assume that many of these costs are not increased substantially when an additional surgical procedure is performed during the same operative session and that a significant payment reduction is appropriate.

In contrast, the pre- and post-procedure activities and resources provided to patients undergoing diagnostic imaging procedures are typically not as extensive as those required for surgical patients. Therefore, the costs associated with pre- and post-service activities are likely to comprise a much smaller portion of the APC payments for diagnostic imaging procedures than for surgical procedures. Consequently, it is unclear to us that extension of the multiple surgical procedure payment reduction to multiple diagnostic imaging services is appropriate.

To determine whether CMS's assertion that the direct practice expense input data used under the physician fee schedule do indeed support the proposed 50 percent reduction in APC payments, the ACC conducted its own analysis of the clinical labor, supply, and equipment inputs associated with the CPT codes within Family 2 (CT and CTA of Chest/Thorax/Abdomen/Pelvis) and Family 4 MRI and MRA of Chest/Abdomen/Pelvis). Results of that analysis follow.

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Clinical labor

CMS identified the following activities as those are not repeated when multiple imaging services are performed during the same session:

- Greeting the patient
- Positioning and escorting the patient
- Providing education and obtaining consent
- Retrieving prior exams
- Setting up the IV
- Preparing and cleaning the room.

According to the process the Practice Expense Advisory Committee (PEAC) established for determining clinical labor time, the activities CMS enumerates as not repeated occur during the pre- and post-service periods. Our analysis of the direct practice expense inputs found that, within Family 2, clinical labor costs associated with pre- and post-service activities average 0.99% of total direct practice expenses. Pre- and post-service clinical labor account for a mean of 0.65% of direct practice expenses for the codes in Family 4. Clearly, these data document minimal clinical labor cost savings when multiple procedures within Families 2 and 4 are performed during the same session.

Supplies

The proposed rule also outlines CMS's assumption that additional supplies, with the exception of film, are not used when more than one imaging procedure within a family is performed. If this were the case we would expect to see little variation in supply costs within a family since supplies of the same type and in the same amount would be used for each procedure. Examination of the practice expense data for Family 2 shows that supply costs range from a low of $10.36 for CPT 74150 to a high of $55.88 for CPT 75635. Within Family 4, supply costs range from $12.02 for 72195 to $28.62 for 72197. The variation suggests that, although certain basic supply items (for example, patient gowns, gloves, and examination table paper) are used for all the procedures within a family, some procedures do require additional, more expensive supplies. However, even CMS's assumption that no additional supplies other than film would be required to perform an additional procedure were valid, actual savings on supplies would be small. Supplies account for an average of 7% of direct practice expenses in Family 2 and 4% in Family 4.

Equipment

The cost of purchasing and maintaining expensive medical equipment accounts for the vast majority of practice expenses associated with diagnostic imaging procedures – an average of 83% of total direct costs in Family 2 and an average of 89% in Family 4. CMS states in the proposed rule that "equipment time... [is] allocated on the basis of clinical staff time and... should be reduced accordingly." Since, as noted above, the clinical staff activities CMS identified as those not duplicated when multiple procedures are performed account for a very small proportion of clinical staff time for the procedures in Families 2 and 4, it seems unlikely that equipment time and, thus, equipment cost would be reduced significantly.

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The ACC acknowledges that some savings in facility costs or physician practice expenses may be achieved when multiple diagnostic imaging procedures are performed on contiguous body parts. However, our analysis of the same data CMS used to support its decision leads us to conclude that an accurate estimate of the savings in the physician office setting would fall far below 50 percent. It is also unclear how accurately data on practice expenses from Medicare's physician fee schedule reflect hospital outpatient facility costs.

The Practice Expense Advisory Committee (PEAC) invested considerable effort in establishing standard times for common clinical staff activities (e.g., greeting the patient, cleaning the room), as well as basic supply packages for similar types of services. Analysis of these standard times and supply packages might provide a more valid basis for a multiple diagnostic imaging payment reduction than does application of a policy developed for surgical services. We urge CMS to conduct a more careful analysis of this issue before implementing a policy that may significantly affect hospitals' ability to provide diagnostic imaging services in the outpatient setting.

Thank you for the opportunity to comment upon this proposed rule. The ACC appreciates CMS' continued willingness to work cooperatively with the provider community to strengthen the Medicare program and improve care for Medicare beneficiaries. Please feel free to contact Rebecca Kelly, ACC's Director of Regulatory Affairs at 301-498-2398 or rkelly@acc.org with any questions.

Sincerely,

Pamela S Douglas

Pamela Douglas, MD, FACC
President

Submitter : Mrs. Catherine Meeter **Date:** 09/15/2005

Organization : Sutter Health

Category : Hospital

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-1501-P-490-Attach-1.DOC

We are seeking further clarification from CMS regarding emergency department patients whose physician has written an order for inpatient admission but the hospital is full (either they have reached their licensed bed capacity or it may have units closed down because of census issues and there is no inpatient bed to transfer a patient to), a transfer is not possible and the patient remains in the ED receiving care after the order is written. There are several scenarios:

- the patient may ultimately be transferred to an inpatient unit and be discharged from that unit **or**
- the patient may never get transferred to an inpatient unit and be discharged from the ED

The RO in San Francisco (Mr. Frank Camozzi) responded to my initial inquiry which reflected the two bullet points above, as follows:

If there is a written order to admit as an inpatient, an inpatient claim should be submitted. Our Central Office is currently working on billing instructions. UGS will put out information once the National instructions are written.

If we bill these patients as inpatients, we are concerned that this may be improper billing because:

- The emergency department bed is not a licensed, inpatient bed. The California Code of Regulations (CCR) Title 22, section 70809 states: "no hospital shall have more patients or beds set up for overnight use by patients than the approved licensed bed capacity except in the case of a justified emergency when temporary permission may be granted by the director or his designee."
- We have concerns about reporting inpatient days that are normally generated from routine nursing units when in fact the patient did not reside nor receive care in a routine nursing area, but remained in the ancillary department of the emergency department. We have concerns regarding accurate reporting of inpatient days on a facility Cost Report.

Previous information, i.e. Q & A from a December 2003 UGS CA-PCOM meeting indicated the following:

(**Q**) *The issue is when a patient is in the emergency department (ED) and the physician writes an order to admit as an inpatient. If the hospital is full, but transfer is not possible, the patient remains in the ED, receiving the appropriate care for their admit status. Could you give some guidance on how this would be billed? Areas to address could include:*

>inpatient status when no beds are available

>billing for services/procedures while still in the ED awaiting a bed opening

>if no bed is assigned, therefore no room and board charge, would UGS accept this claim for an inpatient if it only has other charges without a room and board charge? For example, if the patient remains in the ED for their whole stay and is discharged without ever having gone to an inpatient unit, yet the physician wrote an order for them to become an inpatient.

(**A**) *If a patient is in the emergency department and orders are written by the physician to admit the patient, the care should be continued as ordered in the emergency department until a room is available. When billing Medicare the covered days should only reflect the days in the semi-private room (and not the emergency room) but all charges should be billed and payment will be under the DRG. If beds are not available before the patient is discharged, only part B services can be billed to Medicare on a bill type 12x. This would affect beneficiary payment for deductibles and affect the 3 day stay requirement for transfer to a SNF.*

We wanted to bring this information and our concerns to the attention of CMS to process this information before final instructions were disseminated by CMS. In summary, here are the questions that we hope will be addressed in the final instructions published by CMS:

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- should daily Room and Board charges be generated in both instances/scenarios while the patient is in the ED? (Refer to the first two bullet points in this document)
- what type of bill should be used in both instances? I assume it would be 11x for the patients that transfer to an inpatient unit but what about the patients that never get to an actual inpatient unit?
- should the emergency department continue to charge for separately billable procedures while the patient is in the ED after the order to admit is written?
- Please verify if the patient's stay in the emergency department after the order is written to admit as an inpatient, affects the 3 day stay rule for patients who ultimately get transferred to a SNF?

Submitter : Mr. Dan Perdue **Date:** 09/15/2005

Organization : Wyoming Hospital Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please refer to our attachment

CMS-1501-P-491-Attach-1.DOC

P-491

September 15, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates, CMS-1501-P *Fed. Reg.* 42,674 *et seq,* (July 25, 2005).

Dear Sir or Madam:

On behalf of the membership of the Wyoming Hospital Association, I am pleased to offer our comments on the above referenced Proposed Rule.

Wyoming is a frontier state with approximately five people per square mile in the least populated state in the nation. As such, the healthcare delivery system in the state is extremely fragile, to say the least. Congress established the sole community hospital (SCH) program to provide special protections to hospitals that, by reason of factors such as isolated location, weather conditions, travel conditions, absence of other like hospitals, are the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. All of the hospitals in our state are SCHs that play a critical role in our healthcare infrastructure.

In the proposed rule, CMS discusses the study the agency conducted, in compliance with Section 411 of the Medicare Modernization Act (MMA), to determine if rural hospital outpatient costs exceed urban hospital outpatient costs. As part of this discussion, CMS noted that it conducted an explanatory regression analysis that included three specific classes of rural hospitals – rural SCHs, rural hospitals with less than 100 beds that are not rural SCHs and other rural hospitals. CMS conducted this analysis in order to determine whether the small difference in costs found between rural versus urban hospitals in the initial regression analysis was uniform across rural hospitals or whether all of the variation was attributable to a specific class of rural hospitals. The result of this analysis led CMS to conclude that rural SCHs are more costly than urban hospitals. Therefore, CMS proposes to provide a 6.6 percent payment increase for rural SCHs for 2006, which is extremely welcomed in our state.

I would also like to address the situation affecting Wyoming's two largest hospitals, United Medical Center and Wyoming Medical Center, which are by definition, urban SCHs, but are actually very rural in character. Urban and rural hospitals both must establish that they are the sole source of care in the community they serve. In fact, the qualification criteria are more stringent for urban hospitals, because they have only one

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way in which to qualify for SCH status (an urban hospital may qualify for SCH status only if it is more than 35 miles from another like hospital, whereas a rural hospital can demonstrate its isolation and qualify for SCH status in several ways). Although the area an SCH may serve may be considered urban, the area is nonetheless isolated and otherwise without hospital services. In our state, a good portion of our population is located near our borders, where established referral patterns typically see our residents traveling out of state to seek healthcare. Therefore, all of our hospitals must compete with facilities in Salt Lake City, UT, Billings, MT, Rapid City, SD, Scottsbluff, NE, and Denver, CO to provide care to our own residents. We would urge that CMS adjust OPPS payments for all SCHs regardless of geographic location.

It appears that the proposed rule indicates that many ambulatory payment classification (APC) rates continue to fluctuate dramatically, with payments much lower or higher in 2006 than in 2005. These changes make it extremely difficult for hospitals to plan and budget from year to year. Among these broken APCs, several evaluation and management services APCs – and especially clinic visits – continue to experience declines in payment rates. After four years after the start of the OPPS, the payment rates and associated payment-to-cost ratios would be much more stable. In addition, the entire OPPS is under-funded, paying only 87 cents for every dollar of hospital outpatient care provided to Medicare beneficiaries. Hospitals must have adequate funds to address critical issues such as severe workforce shortages, skyrocketing liability premiums, the rising cost of drugs and technologies, aging facilities, expensive regulatory mandates and more.

We appreciate the opportunity to provide these comments. If you have any questions, please don't hesitate to contact me.

Dan Perdue
Vice President
Wyoming Hospital Association
2005 Warren Avenue
Cheyenne, WY 82001

Submitter : **Dr. Todd Brandt** **Date: 09/15/2005**

Organization : **Metro Urology**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Dear Dr. McClellan,

I am a urolgist with special expertise in cryosurgical treatment of urologic cancers, specifically prostate cancer. My concerns relate to the proposed 2006 payment rates for outpatient cryosurgical ablation of the prostate for treatment of prostate cancer (APC 674). The proposed reimbursement is just over 5,000 dollars and it is my understanding that this procedure may cost the hospital over 9,000 dollars to perform. I urge you to reconsider the proposed rate of reimbursement. I fear that my hospital would not allow me to perform the procedure if the hospital stands to lose money on each case. I have seen the benefits of cryosurgery for my patients when I began to perform the procedure about two years ago; my local hospital and my patients have also seen the distinct advantages this type of procedure offers to certain patients, specifically the older patient who enjoys a quicker recovery from this procedure than from traditional approaches to prostate cancer treatment such as radical prostatectomy. I urge you to consider a review and revision of the proposed reimbursement of APC 674.

Todd D Brandt MD

Submitter : Ms. Bonnie Handke
Organization : Medtronic, Inc
Category : Device Industry

Date: 09/15/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachments

CMS-1501-P-493-Attach-1.DOC

CMS-1501-P-493-Attach-2.DOC

CMS-1501-P-493-Attach-3.DOC

CMS-1501-P-493-Attach-4.RTF

CMS-1501-P-493-Attach-5.RTF

CMS-1501-P-493-Attach-6.RTF

ATTACH #1

Calendar Year 2004 Data
Hospital Acquisition Costs For Pacemaker, CRT-P, ICD, and CRT-D Devices
[Median, Mean, (N)]

Technology	APC	2005 Total APC Payment[1]	CMS 2005 Device Related Portion of APC[2] (APC % attributed to device)	Goodroe[3]	IMS Health[4]	Premier[5]
Single chamber pacemaker system (pulse generator and electrodes)	0089	$6,244.35	$4,896.19 (78.41%)	$5,394 $5,604 (92)	$4,959 $5,030 (34,945)	$5,854 $6,047 (13,198)[8]
Single chamber pacemaker pulse generator only	0090	$5,159.42	$4,093.48 (79.34%)	$4,900 $4,904 (97)	$4,269 $4,329 (34,945)	$4,497 $4,499 (13,198)[8]
Pacemaker system (dual chamber and CRT-P)	0655	$7,701.05	$6,280.21 (81.55%)	$7,134 $7,217 (470)	$6,649 $6,988 (141,535)[7]	NA
Pacemaker generator only (dual chamber and CRT-P)	0654	$6,004.90	$4,868.17 (81.07%)	$5,635 $5,587 (548)	$5,149 $5,482 (141,535)[7]	NA
Pacemaker leads only	0106	$3,142.27	$1,918.36 (61.05%)	$723 $734 (1,319)	$690 $702 (268,122)	$753 $859 (24,198)[9]
ICD system (pulse generator and electrodes, includes CRT-D)	0108	$24,121.71	$22,655.11 (93.92%)	$27,592 $27,734 (368)	$24,824 $26,213 (108,936)[6]	$25,763 $26,431 (7,120)
ICD pulse generator only (includes CRT-D)	0107	$17,963.71	$16,629.01 (92.57%)	$19,029 $19,409 (296)	$18,402 $19,600 (108,936)[6]	$20,819 $21,522 (7,120)
ICD leads only	0106	$3,142.27	$1,918.36 (61.05%)	$5,855 $5,494 (374)	$5,162 $5,454 (50,895)	$4,397 $4,499 (7,239)
Resynchronization (left ventricular) lead only	1525	$3,750.00	N/A	$2,487 $2,672 (119)	$2,664 $2,279 (31,891)	NA

1 Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2005 Rates; Final Rule. Federal Register November 15, 2004
2 Source: CMS website, http://www.cms.hhs.gov/providers/hopps/2005fc/1427fc.asp
3 Goodroe Healthcare Solutions, CathSource™ database for January 1, 2004 through December 31, 2004.
4 IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2004 through December 31, 2004
5 Premier Healthcare Informatics, Perspective Comparative Database for January 1, 2004 through December 31, 2004
6 IMS Health, Hospital Supply Index device mix is 27.3% single chamber, 44.2% dual chamber, and 28.5% CRT-D
7 IMS Health, Hospital Supply Index device mix is 95.5% dual chamber and 4.5% CRT-P
8 Costs include single chamber, dual chamber, and CRT-P
9 Costs include left sided leads

Attachment # 2

1

September 6, 2005

Mark McClellan, MD, PhD, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–1501- P
7500 Security Blvd.
Baltimore, MD 21244-1850

ELECTRONICALLY SUBMITTED

Re: Hospital Outpatient Prospective Payment System
Proposed Rule [CMS-1501-P]
Update for Calendar Year 2006

Dear Dr. McClellan:

Medtronic, Inc. is one of the world's leading medical technology companies specializing in implantable and interventional therapies that alleviate pain, restore health, and extend life. We are committed to the continual research and development necessary to produce high quality products and to support innovative therapies that improve patients' health outcomes. We appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule on Changes to the Medicare Outpatient Prospective Payment System and Payment Rates for Calendar Year 2006 (CMS-1501-P, *Federal Register*, Vol. 70, No.141, Monday, July 25, 2005, p.42674).

Medtronic appreciates the significant effort you and your staff have put into the outpatient prospective payment system (OPPS). We also appreciate your release of the 2004 outpatient hospital claims database and willingness to work with us to preserve beneficiaries' access to the full range of treatment options in the outpatient setting.

As with previous years, we have studied and compared the 2003 and 2004 OPPS data used to set payment rates under the OPPS system. We appreciate the steps taken by CMS to increase the number of claims used to determine the 2006 payment rates. However, as evidenced by the median cost data significant issues continue to persist in the quality of claims data for services involving higher-cost medical technologies. Although some improvement is seen in the 2004 data used for the 2006 update as compared to the 2003 data, the OPPS

data continue to inadequately reflect the costs of higher cost implantable devices and associated procedures. In the past, CMS was able to use the C-code screening mechanism blended with external, third party data to arrive at the device portions used for a limited set of APCs. We are concerned with the 2006 NPRM approach basing median costs for some device dependent APCs on *the greater of (1) median costs calculated using CY 2004 claims data or (2) 85% of the payment median for CY 2005 for such services.* We agree that some variation in median costs can be expected from year to year. However, we do not concur that an arbitrary 15% downward swing is appropriate or expected for devices that have not been well represented in the claims data historically. Most, if not all of these APCs were also subject to the floor in CY2005. The cumulative reduction over these two years is greater than hospitals can sustain – especially considering that many of the APC payment rates already do not cover the acquisition cost of the device, without regard for the procedural component.

The impact of the reduction on higher cost implantable devices will likely result negatively on patient access. This proposal creates an unsustainable financial burden for hospitals that provide these services. As we have heard from members of the APC Advisory Panel at recent meetings, many of these APCs are already experiencing payment disincentives that reduce beneficiary access to care in the outpatient hospital setting, which is typically less-costly than other available sites of service, especially hospital inpatient care which is the primary alternative for these services.

To address these and other issues, we are recommending specific adjustments to improve the OPPS system and ensure beneficiary access to appropriate care. We believe that substantive two-way discussion is necessary to ensure successful implementation of the OPPS system. We continue to raise concerns over numerous issues surrounding the OPPS payments. We also continue to suggest potential solutions. We believe these issues are complex and the only way they will be fully resolved is if the communication between the agency and manufacturers continues.

We will comment and provide recommendations on the following topics:

- **APC Payment Rates for Medtronic Products**
- **Device Dependent APCs - Proposed Method of Adjusting Median Costs for CY2006**
- **Use of External Data**
- **Mandatory Reporting of C-Codes**
- **New Technology APCs**
- **Charge Compression**
- **APC Panel Recommendations**
- **Criteria for Establishing New Pass-through Device Categories**
    - **Surgical Insertion and Implantation Criterion**
    - **Existing Device Category Criterion**
- **Other**

I. APC Payment Rates

Inadequacy of APC Payment Rates for Key Medtronic Products
As CMS works on changes to the OPPS program, we continue to urge the agency to ensure that base APC payment rates are adequate to cover both the device and procedure costs. We continue to be concerned that many APC payment levels do not reflect medical technology costs and are grossly inadequate.

While we have concerns with other device-related APC payment rates, we have highlighted the APCs and products below because of the level of payment rate inadequacy, and the magnitude of dollars involved for the hospitals on a per-procedure basis.

I am appreciative of the opportunity Medtronic staff has had to meet with CMS on several occasions prior to and after the release of the proposed rule. We have included all of the presentations made during these meetings as attachments to this letter for your reference.

Insertion of Cardioverter-Defibrillator Pulse Generator (APC 0107)
Insertion of Cardioverter-Defibrillator System (APC 0108)
CMS proposes an APC payment for the insertion of the cardioverter-defibrillator generator (APC0107) of $15,430.93. This amount represents a 14.1% reduction over the 2005 payment rate and is just 84% of the lowest median hospital acquisition cost of the device ($18,402 - $20,819, based on external data sources [1,2,3]), leaving the hospital with both an out-of-pocket loss for the device as well as no payment for the implant procedure. According to the CMS' Device Related Portions of APC Costs for 2005, the device cost associated with APC 0107 was $16,629.01, or 92.57% of the 2005 APC payment rate. In other words, the non-device or procedural costs associated with APC 0107 were $1,334.70. Therefore, under the proposed payment rate, the hospital would incur an immediate loss of over $2,970 on just the lowest acquisition cost for the device and ultimately, a loss of over $4,300 for the device and the procedure costs per procedure when performing a cardioverter-defibrillator generator implant.

CMS proposes an APC payment for the insertion of the cardioverter-defibrillator system (APC 0108) of $20,720.68. Similar to the payment rate for APC 0107, the payment rate for APC 0108 represents a 14.1% reduction over the 2005 payment rate and is just 84% of the lowest median hospital acquisition cost of the device ($24,824 - $27,592, based on external data sources[1,2,3]), leaving the hospital with both an out-of-pocket loss for the device as well as no payment for the implant procedure. According to the CMS' Device Related Portions of APC Costs for 2005, the device cost associated with APC 0108 was $22,655.11, or 93.92% of the 2005 APC payment rate. In other words, the non-device or procedural costs associated with APC 0108 were $1,466.60. Therefore, under the proposed payment rate, the hospital would incur an immediate loss of over

[1] IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2004 through December 31, 2004

[2] Goodroe Healthcare Solutions, CathSource™ database for January 1, 2004 through December 31, 2004
[3] Premier Healthcare Informatics, Perspective Comparative Database for January 1, 2004 through December 31, 2004

$4,100 on just the lowest acquisition cost for the device and ultimately a loss of over $5,500 for the device and the procedure costs per procedure when performing a cardioverter-defibrillator system implant.

If the outpatient proposed rates for APCs 0107 and 0108 are carried over to the final rule, these APCs will have incurred reductions of 20.5% and 29.4% respectively since 2002. These reductions create an untenable financial burden for hospitals seeking to provide care in the appropriate clinical setting to Medicare beneficiaries. No aspect of healthcare has experience such a decline in payment.

Medtronic recommends that CMS preserve beneficiaries' access to this life-saving therapy in the outpatient setting by following the August 2005 APC Advisory Panel recommendation to use 2005 payment rates plus the 3.2% hospital update for these APCs when determining the final 2006 payment rates for APCs 0107 and 0108. We have attached the external data as submitted previously and presented at the APC Advisory Panel meeting.

CMS Modeling of February 2005 APC Panel Recommendations Pertaining to APC 0107 and APC 0108

Prompted by a recommendation from the February 2005 APC Advisory Panel, CMS modeled four possible scenarios in the NPRM to increase the number of single bills used for rate setting for APC 0107 and APC 0108. Although the scenarios displayed in Table 16 of the NPRM increase the number of possible single bills used for rate setting for these APCs, as seen in the adaptation of Table 16 below, the resulting median costs are still greatly undervalued in comparison to the device acquisition costs. It is important to note that the cost underestimation associated with each scenario is based solely on the device acquisition costs and the underestimation would further increase if the procedural costs were taken into account in this analysis.

We do not recommend that CMS proceed with any of these options. Although the scenarios may increase the number of single billed claims, the single billed claims to not correctly estimate the costs associated with these procedures. This underestimation, which has occurred every year since the inception of OPPS, may, in part, be attributed to the influences of charge compression.

APC 0107

Scenario	APC 0107 Using unadjusted median cost	APC 0107 Using adjusted median cost	APC 0107 With panel changes	Range of cost underestimation when compared to median external device acquisition cost ($20,819[1])
(A) Median total if device is inserted only (neither removal nor testing)	$15,166.64	$15,691.08	$15,961.14	**$4,855 - $5,652** below device acquisition costs
(B) Median total if device is inserted and tested (no removal)	$15,771.31	$16,295.75	$15,961.14	**$4,523 - $5,048** below device acquisition costs
(C) Median total if device is removed and inserted (no testing)	$15,841.54	$16,365.98	$16,636.04	**$4,183 - $4,977** below device acquisition costs
(D) Median total if device is removed, inserted and tested	$16,446.21	$16,970.65	$16,636.04	**$3,848 - $4,373** below device acquisition costs

[1] *Premier Healthcare Informatics, Perspective Comparative Database for January 1, 2004 through December 31, 2004.*

APC 0108

Scenario	APC 0108 Using unadjusted median cost	APC 0108 Using adjusted median cost	APC 0108 With panel changes	Range of cost underestimation when compared to median external device acquisition costs ($24,824[1])
(A) Median total if device is inserted only (neither removal nor testing)	$18,165.78	$21,070.02	$21,517.00	**$4,246 - $7,597** below device acquisition costs
(B) Median total if device is inserted and tested (no removal)	$18,770.45	$21,674.69	$21,517.00	**$4,088 - $6,993** below device acquisition costs
(C) Median total if device is removed and inserted (no testing)	$18,840.68	$21,744.92	$22,191.90	**$3,571 - $6,922** below device acquisition costs
(D) Median total if device is removed, inserted and tested	$19,445.35	$22,349.59	$22,191.90	**$3,413 - $6,318** below device acquisition costs

[1] *Premier Healthcare Informatics, Perspective Comparative Database for January 1, 2004 through December 31, 2004*

Implantation of Pump and Neurostimulators (APCs 0039, 0222, 0227 and 0315)

The proposed payment for APCs 0227, 0039, 0222 and 0315 will not adequately cover the median acquisition cost of the devices and the procedural component. There are significant differences between the claims data calculation of device costs compared to the reported device acquisition costs by IMS Health.

Implantation of Infusion Pump (APC 0227)

APC	Proposed Payment 2006	Device Related %[1]	Device Related Portion	IMS Health Average Cost[2]	Difference between CMS Device portion and IMS Data
0227	$8,099.86	82.12%	$6,651.60	$9,755.00	($3,103.40)

[1] *Device Related % from CMS Device Related Portions of Ambulatory Payment Classification Costs for 2005.*
[2] *IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2004 through*

December 31, 2004.

Neurostimulators (APCs 0039, 0222, 0315)

APC	Proposed Payment 2006	Device Related %[1]	Device Related Portion	IMS Health Average cost[2]	Difference between CMS Device portion and IMS Data
0039	$10,764.82	79.71%	$8,580	$10,635	($2,055)
0222	$10,628.22	86.19%	$9,160	$11,370	($2,210)
0315	$17,247.86	79.71%[3]	$13,748	$17,246	($3,498)

[1] *Device Related % from CMS Device Related Portions of Ambulatory Payment Classification Costs for 2005.*
[2] *IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2004 through December 31, 2004.*
[3] *Device portion not published for APC 0315, 0039 device portion used due to similarity of procedure.*

Examples of potential hospital losses for Infusion Pump and Neurostimulator APCs:

APC	IMS Health Average Cost[1]	Procedural Component[2]	Sum	2006 Proposed Payment	Difference between Payment and Cost
0227	$9,755	$1,532	$11,287	$8,099	($3,188)
0039	$10,635	$2,543	$13,178	$10,764	($2,414)
0222	$11,370	$1,709	$13,079	$10,628	($2,451)
0315	$17,246	$2,543	$19,789	$17,247	($2,542)

[1] *IMS Health, Hospital Supply Index of non-federal, short-term acute care hospital purchases for January 1, 2004 through December 31,2004.*
[2] *Procedural component calculated from CMS Device Related Portions of Ambulatory Payment Classification Costs for 2005.*

We remain especially concerned about APC 0315. This APC was established in 2005 to reflect new bilateral technology to treat Parkinson's disease. The APC payment was based on procedural related costs from APC 0039 and device related costs submitted by Medtronic. In the 2005 final rule it was recognized that reporting issues existed with CPT code 61886; it is apparent from review of the current data that the issue has continued. Only 28% (88) of the total claims have a primary diagnosis of Parkinson's disease. Additionally, approximately 29% (89) of the claims also included a C-code; however only 30% (27) of those claims were for Parkinson's disease.

We recommend that CMS base 2006 payment rates on 100% of 2005 payments plus the update for APCs 0107, 0108, 0227, 0039, 0222, and 0315. It is important to note that this does not completely solve the issues for these APCs. We strongly encourage CMS to convene and lead a broad stakeholder panel including hospitals, provider, industry representatives and others to discuss and provide potential solutions for future years. This recommendation is discussed further below.

II. Device Dependent APCs Proposed Method of Adjusting Median Costs for CY2006

We are concerned with the 2006 NPRM approach basing median costs for some device dependent APCs on the greater of (1) median costs calculated using CY 2004 claims data or (2) 85% of the payment median for CY 2005 for such services. We agree that some variation in median costs can be expected from year to year. However, we do not concur that an arbitrary 15% downward swing

is appropriate or expected for devices that have not been well represented in the claims data historically. Many, if not all, of these APCs were also subject to decreases in CY2005. Cumulative decreases for some of these APCs are greater than 30%.

We recommend that CMS base CY 2006 payment rates on 100% of CY 2005 payment medians plus the update for the following APCs: 0107, 0108, 0222, 0039, 0315 and 0227. External data submitted by Medtronic and other manufacturers demonstrates that these APCs will be significantly underpaid at the proposed rates.

III. Use of External Data

The APC Panel has recommended that CMS address the problem of poor and inadequate hospital claims data regarding devices by incorporating external data into the median cost calculations. Medtronic has submitted external data from reliable third party vendors (IMS Health, Premier and Goodroe) every year. We remain concerned that CMS did not make any adjustments using external data in 2005 and in the 2006 proposed rule did not make any indication that they would even consider the external data. In fact, CMS has commented that they fully expect to base the rates solely on claims data in the development of the 2007 APC payment rates.

While Medtronic conceptually shares CMS' vision of developing OPPS payment rates solely based on hospital claims data, we believe that this is not a currently a possibility given the clearly demonstrated inaccuracies in the data. Developing the rates solely on the current claims data is not an option until the data are appropriate to be used in such a manner. Medtronic is very concerned that CMS continues to risk beneficiary access by overlooking known issues with the accuracy of the data as it relates to certain devices. For the last four years, the external data clearly validate that the median costs computed from the claims data under-represent technology costs, yet the agency continues to utilize these data in the development of the APC payment rates over external data from reliable third party vendors. If CMS maintains its position of utilizing the inaccurate claims data and does not take into account these external data sources or employ a new methodology for rate setting, it is safe to expect continued declining APC payments which will ultimately result in beneficiary access issues to potentially life-saving devices.

IV. Mandatory Reporting of C Codes

Medtronic continues to support the reinstitution of c codes. We urge CMS to educate hospitals regarding the importance of reporting c codes for all devices whether or not an edit is in place. While the presence of c codes alone is not expected to solve the claims data problem nor the charge compression issue with higher cost devices, it may improve the overall quality of claims used to set APC payment rates. We believe it is critical that hospitals be required to continue reporting the c codes.

In an effort to educate hospitals regarding the importance of appropriate coding,

Medtronic has and will continue to work directly with hospitals that implant our devices. Since the inception of the OPPS program, we have provided product-specific pass-through code lists and have devoted field representatives to the sole purpose of hospital education regarding reimbursement, payment, and billing. However, Medtronic and our colleagues have been limited in our ability to impact hospital behavior due to an overall reticence of hospitals to accept guidance from anyone other than the payer (Medicare), especially in light of the increased scrutiny that surrounds hospital charging and billing.

We also want to add that this educational effort needs to include information on billing c codes for New Technology APCs and how that differs from billing c codes for devices. It has been suggested that when billing for New Technology APCs, hospitals need to incorporate charge information for all the resources used, to include items such as nursing support, capital equipment and other overhead, in addition to the device. If hospitals just assume that c codes are uniformly dedicated to billing for devices, the costs associated with New Technology APCs will be understated as they are transitioned to clinical APCs. We are very concerned that there has been tremendous confusion related to correct billing for the New Technology APCs and believe that this is evidenced by the inadequate rates many procedures have been subjected to when they are moved from a New Technology APC to a clinical APC.

We encourage CMS to assist in our education efforts by becoming more actively involved in offering guidance to hospitals not only on the importance of c code billing, but also on the importance of appropriately charging for high-cost devices so that future updates to the OPPS will more accurately reflect hospital costs.

V. New Technology APCs

CMS is proposing to require that an application for a code be submitted to the American Medical Association's (AMA) CPT Editorial Panel for a new technology before CMS will accept a New Technology APC application for review. CMS is also proposing to require that a copy of the submitted CPT application (for either a Category I or III code) be filed with CMS as part of the application for a New Technology APC, along with a letter from the CPT Editorial Panel acknowledging the CPT code application. While Medtronic acknowledges CMS' intentions in aligning the CPT and New Technology APC processes, the logistics of this requirement, if adopted in the final rule, will ultimately slow beneficiary access to new technologies.

Within the NPRM, CMS indicates that "consideration by the CPT Editorial Panel may facilitate appropriate dissemination of new technology" and "may bring to light other needed coding changes or clarifications". However, requiring the submission of a CPT application and subsequent acknowledgement letter from the AMA will result in delays in the dissemination of new technology. This process requires manufacturers or medical specialty societies to apply for CPT codes prior to the availability of sufficient evidence, potentially resulting in the arbitrary assignment of a Category III code by the AMA. This coding assignment can be detrimental to the patient access to new services or technologies

because CPT Category III codes are not often paid for up to two years after FDA approval, particularly in the private payer community.

The proposed requirement also will not facilitate the "clarification" for which CMS is seeking because the calendars/timelines associated with the CPT coding and New Technology applications are not well coordinated. For example, in 2006 the first CPT application deadline is March 8th, 2006, which is seven days after the first New Technology APC application deadline of March 1st, 2006. Under the CPT calendar, the CPT application submitted to meet the March 8th deadline would not even be reviewed by the CPT Editorial Panel until the June 8th – 11th meeting. This is just three weeks prior to the July 1st effective date of the coordinating New Technology APC. Clearly, the timelines for the application processes will not allow for the type of process alignment and clarification for which CMS is hoping to achieve by requiring the CPT application to be submitted prior to the application of a New Technology APC.

Because of the potential impact on beneficiary access to new technologies that would result from this proposed change, we request that CMS not require the submission of a CPT code application before it accepts a New Technology APC application for review. An alternative to the changes proposed in the NPRM would be to issue the New Technology APC for one year, making the continuation of the New Technology status contingent on the receipt of the CPT application and acceptance letter. This approach would allow CMS to realize the benefits of the alignment in the CPT and New Technology APC processes without negatively impacting patient access.

Left Ventricular Lead (CPT 33225)

CMS is proposing to move CPT 33225 (Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of pacing cardioverter-defibrillator or pacemaker pulse generator) from New Technology APC 1525 to clinical APC 0418. While clinical homogeneity is established with the APC change, the status indicator "S" that was previously assigned to APC 1525 is not carried over to APC 0418. Although the payment rate for the implant would increase from $3,750 to $6,458 with the change in APC, the change in the status indicator subjects the procedure to a 50% reduction in multiple procedure scenarios.

The assignment of status indicator "T" does not adequately represent the additional procedural time and resources associated with this service. The left ventricular lead (33225) requires a totally different procedural aspect and approach than that of the primary procedures (33208 or 33249) commonly billed with it. The different procedural aspect is recognized for the physician billing by the AMA CPT which classifies the left ventricular lead implant (33225) as an add-on code, not subject to the multiple procedure reduction.

Normally conventional pacemaker procedures take about 1 hour. Placement of the left ventricular lead can add at least an additional hour to the procedure consuming additional hospital resources and time not accounted for with the

status indicator "T". In addition to the added time associated with the implant procedure, it should be recognized that a large portion of the cost associated with any left ventricular lead implant is the lead itself, which is a cost that would not be reduced regardless of the other procedures performed in conjunction with the lead implant.

Medtronic believes code 33225 requires a separate procedural approach resulting in additional time and resources for completion of the implant. Medtronic requests that CMS maintain the current status indicator "S" for code 33225.

New Technology/Pass - Through Process

Medtronic urges CMS to make changes to the Pass-though/New Tech APC Application process so that it becomes more transparent and predictable. We note that under the current approach followed by CMS, there is no public disclosure of applications that have been filed with the agency and there is often no opportunity for the public to comment on the disposition of proposed or final actions on pass through or new-tech APC applications. Lack of public information about pending applications constrains manufacturer reimbursement planning efforts and results in a closed agency process that limits public input.

We believe CMS can make the pass through and new-tech APC payment mechanisms more open by adopting some of the processes used in the inpatient new-technology add-on program, while retaining the quarterly update capabilities. For example, CMS posts tracking sheets on its website for all applications submitted by manufacturers for inpatient add-on payments. CMS holds a town-hall meeting for the public to comment on the "substantial improvement" aspects of each technology under consideration. And CMS provides a summary of the issues surrounding each application and allows for public comment on each application in the annual inpatient proposed rule. We believe actions similar to these can be adopted on the outpatient side to make the pass-through and new-tech APC programs more fair, open, and predictable while retaining the quarterly update capability.

VI. Charge Compression

It has been seen that hospitals are reluctant to charge high enough under CMS's current cost-to-charge methodology to reflect actual acquisition costs for higher cost devices. As seen in the chart below, charge data for higher-cost technologies demonstrate that hospitals do not appear to be marking up these technologies at the same rate as other lower cost items. For instance, in the chart below, the mark-up for ICD pulse generators is 79% lower than other less costly devices.

Device Type	Number of Hospitals	Percentage Mark-Up (Mean) [1]
Pacemaker Lead	111	266
Pacemaker Pulse Generator	111	221
ICD Lead	69	221
ICD Pulse Generator	**60**	**142**

[1] *Premier Healthcare Informatics, Perspective Comparative Database for January 1, 2004 through December 31, 2004*

As a result, CMS's current application of cost-to-charge ratios provides an underestimation of the hospital's costs for these items, undermining the base APC rates for many APCs associated with higher cost devices, such as cardioverter-defibrillator implants.

In an effort to educate hospitals regarding the importance of appropriate coding, Medtronic has and will continue to work directly with hospitals that implant our devices. The reticence of hospitals to modify their charge practices has clearly limited our ability to make an impact on the charge practices of hospitals. In addition, the current cost-to-charge methodology used by CMS to determine hospital costs is sometimes in direct conflict with the payment mechanisms of private payers and contractual obligations hospitals hold with these payers. This leaves hospitals with no other choice than to bill charges they know will under represent their true costs.

We recommend that CMS convene and lead a broad stakeholder panel to address the charge compression issue. We believe that it is imperative that CMS lead and initiate this effort due to the complexity of the issue. Resolution of the charge compression phenomenon will improve the quality of the claims data used to set future payment rates and ultimately improve beneficiary access to life saving technologies.

VII. August 2005 APC Panel Recommendations

Medtronic along with other industry representatives participated in the August 17th -18th APC Advisory Panel Meeting held in Baltimore. The panel made the following recommendations based on presentations given by hospital administrators, physicians and representatives on behalf of the manufacturers.

Device-Related APCs
APCs - 0107 and 0108
The Panel recommends that for 2006, CMS base the payment rates for APCs 107 and 108, which provide payments for cardioverter defibrillator implantations, on their 2005 payment rates plus 3.2 percent.

Neurostimulator Electrode APCs Proposed Reconfiguration
The Panel recommends that CMS adopt the proposed reconfiguration of APCs 040 and 225 for neurostimulator electrode implantation as submitted by Medtronic, creating three APCs that are clinically homogenous and coherent in use of resources. As proposed, APC 040 would include CPT codes 63650, 64555, 64560, **64565** and 64561; APC 225 would include CPT codes 64553 and

64573; and a new APC would include CPT codes 64577, 64580, 64575, 64581, and 63655.

64565 was inadvertently omitted from the panel recommendation as posted on the CMS website, however, was part of the recommendation proposed and unanimously recommended by the panel.

Medtronic fully supports both recommendations made by the panel and encourages CMS to implement both. Copies of supporting materials presented at the APC Panel are attached to this letter.

VIII. Criteria for Establishing New Pass-through Device Categories

Surgical Insertion and Implantation Criterion

We commend CMS for soliciting comments on the criterion related to pass-through eligibility for new devices which are inserted or implanted through an orifice. Further, CMS is to be commended for recognizing that a traditional definition of surgical incision limits access to innovative, less invasive technologies that can be inserted through an orifice. These technologies offer benefits for Medicare beneficiaries and avoidance of more invasive, costly surgery.

By way of implementation, CMS proposes to modify the current interpretation of regulations § 419.66(b)(3) to consider devices pass-though eligible if inserted or implanted through a natural or surgically-created orifice within the scope of surgically implanted devices, as well as those that are inserted or implanted through a surgically created incision. While this interpretation resolves the need to establish the existence of a traditional surgical incision to insert/implant a device through an orifice, we suggest that regulatory language be modified to institutionalize this change. Current language reads:

> Sec. 419.66 Transitional Pass-through Payments
>
> (b)(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital.

We request consideration to change the regulation to read:

> (b)(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is implanted or inserted, through a natural or surgically created orifice or through a surgically created incision, whether or not the device remains with the patient when the patient is released from the hospital.

Existing Device Category Criterion

CMS has proposed to revise Sec 419.66 (c) (1) of the regulation. This revision proposes to apply two tests based on their evaluation of information provided to them in the device category application.

1. An applicant must show that the device is not similar to devices (including predicate devices) whose costs are already reflected in the claims data.

2. An applicant must demonstrate that utilization of their device provides a substantial clinical improvement for Medicare beneficiaries compared with currently available treatments.

Medtronic fully supports this proposal and urge CMS to finalize.

Furthermore, Medtronic has a pending pass - through application for which we believe this proposal would apply. A pass - through application was made in early 2005 for the Restore Rechargeable Neurostimulator. As you are aware, this technology was approved for a New Technology Add-On Payment under the Hospital Inpatient Prospective Payment System.

It is our belief that this technology meets the two part test under the following rationale.

1. **It is not similar to devices whose cost is currently reflected in outpatient claims data.**

   Rechargeable neurostimulators, Radio Frequency (RF) neurostimulators and non-rechargeable neurostimulators are distinctly different technologies. Radio Frequency neurostimulators require an external power source that must be worn continuously for therapy to be delivered. This power source is not rechargeable. Studies have demonstrated lower patient compliance with this type of device due to skin breakdown, irritation and other issues. Rechargeable neurostimulators have an internal power source that is recharged once every 3-6 weeks using an external recharger that the patient wears for a short period of time. Patients are able to receive the therapy continuously without concern for battery life or skin irritation and breakdown. Non-rechargeable neurostimulators also have an internal power source, however it is not rechargeable. Upon depletion of the battery, the patient must undergo replacement surgery to continue receiving the therapy. Patients are also able to receive therapy continuously.

2. **Provides substantial clinical improvement.**

   Rechargeable neurostimulators represent a significant clinical improvement over existing technology. Rechargeable technology provides more treatment options for those patients requiring high energy stimulation. Prior to the approval of rechargeable neurostimulators, patients with high energy needs often underwent frequent neurostimulator replacement or they were unable to

experience the full benefit of neurostimulation due to battery conservation. Rechargeable technology provides for a reduction in surgeries related to neurostimulator replacement caused by battery depletion. Additionally, it allows physicians to use two16-electrode leads instead of the 8-electrode leads used in older neurostimulators. By using leads with more electrodes, physicians can place the leads so that more coverage is provided to the spinal nerves. This also provides for the option to reprogram the neurostimulator if a lead migrates after implantation, thereby avoiding an invasive surgery for lead revision. Medtronic device registry data has demonstrated that 34% of patients aged 54 and older, who receive non-rechargeable devices; require replacement surgery within 10 years of implant. More than half of those patients have high energy needs that deplete the battery within the first three years. As previously stated, rechargeable technology provides for the avoidance of these battery replacement surgeries. Additionally, it has been demonstrated that patient compliance is vastly improved with rechargeable technology.

IX. Other

CPT 91035 – Esophagus, gastroesophageal reflux test; with mucosal attached telemetry pH electrode placement, recording, analysis and interpretation

Beginning in April 2004, this procedure was designated as eligible for new technology APC status and assigned to APC 1506 when billed with C9712. CPT 91035 became effective for this procedure on January 1, 2005 replacing use of the C-code. The code was assigned to APC 1506 *New Technology - Level VI*. In the 2006 proposed rule that was published in the July 25, 2005 *Federal Register*, CMS proposed to move CPT 91035 from APC 1506 to APC 0361, *Level II Alimentary Tests*.

We submitted a presentation to the APC Advisory Panel detailing our concerns related to costs and lack of clinical coherence with movement of this procedure to APC 0361. Thank you for recognizing that the proposed APC change was an error and that no presentation to the APC Advisory Panel was necessary. As per the August 26 *Federal Register* correction notice, CPT 91035 is proposed to remain in APC 1506. We appreciate the agency's prompt and appropriate response to our concerns.

Status Indicator APC 0223/0227

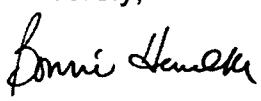
The multiple procedure reduction rule should not apply in the case where procedures to implant a catheter and implantable infusion pump are performed during the same operative session. The reductions are intended to account for efficiencies in hospital resources (staffing, procedure room preparation, scheduling, etc.) when two procedures are performed during the same outpatient episode. While there are efficiencies in performing multiple procedures for non-device dependant APCs and the reduction is appropriate, it is not appropriate for device dependant APCs, where the majority of hospital costs are related to the purchase of the device. External data shows that the vast majority of time,

implantation of the catheter and infusion pump occur during the same operative session. The 50% reduction on the catheter APC does not cover the procedural and device related costs.

We urge CMS to change the status indicator for APC 0223 from a "T" to an "S".

In closing, outpatient services represent a critical means for patient access to innovative and life-saving medical technology. It is critical that OPPS provide appropriate payment for these services to assure continued Medicare beneficiary access. We appreciate the opportunity to submit these comments. Questions or requests for additional information on these comments should be directed to Bonnie Handke at (763) 505-2748.

Sincerely,



Bonnie J. Handke, RN
Sr. Manager, Health Policy and Payment
Medtronic, Inc

Attachments

Attachment #3

Medtronic Neurological
710 Medtronic Pkwy NE
Fridley, MN 55432 USA
www.medtronic.com

September 15, 2005

Mr. Barry Levi
Department of Outpatient Care
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail stop C4-07-14
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates
Pass-Through Device Categories

Dear Mr. Levi:

Medtronic, Inc. is one of the world's leading medical technology companies, specializing in implantables and interventional therapies that alleviate pain, restore health and extend life. Medtronic Neurological appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule on Changes to the Medicare Outpatient Prospective Payment System and Payment Rates for CY 2006, published in the *Federal Register* on July 25, 2005. Our comments that follow are related to Pass-Through Device Categories.

Medtronic fully supports Medicare's proposal to create an additional category for devices that meet all of the criteria required to establish a new category for pass-through payment in instances where an existing or previously existing category descriptor does not appropriately describe the new type of device. We also support CMS' application of the two tests to determine eligibility and we urge CMS to finalize this proposal.

Furthermore, Medtronic has a pending pass through application for which we believe this proposal would apply. A pass through application was made February, 28, 2005 for Restore™, Medtronic's rechargeable implantable neurostimulator for the treatment of chronic, intractable pain. As you are aware, this technology was approved, effective October 1, 2006, for a New Technology Add-On Payment under the Hospital Inpatient Prospective Payment System. It is our belief that this technology meets the two part test under the following rationale.

1. **It is not similar to devices whose cost is currently reflected in outpatient claims data.**
   Rechargeable neurostimulators, Radio Frequency (RF) neurostimulators and non-rechargeable neurostimulators are distinctly different technologies. Radio Frequency

neurostimulators require an external power source that must be worn continuously for therapy to be delivered. This power source is not rechargeable. Studies have demonstrated lower patient compliance with this type of device due to skin breakdown, irritation and other issues.

Rechargeable neurostimulators have an internal power source that is recharged once every 3-6 weeks using an external recharger that the patient wears for a short period of time. Patients are able to receive the therapy continuously without concern for battery life or skin irritation and breakdown. Non-rechargeable neurostimulators also have an internal power source, however it is not rechargeable. Upon depletion of the battery, the patient must undergo replacement surgery to continue receiving the therapy. Non-rechargeable neurostimulators also provide continuous therapy.

The earliest available implantable rechargeable neurostimulator was the Precision™ Spinal Cord Stimulation System, manufactured by Advanced Bionics Corporation, which received FDA approval on April 2004. Precision™ Spinal Cord Stimulation System became available for commercial distribution on a limited basis in June 2004. All other currently available rechargeable neurostimulators, Restore™, Genesis®, and Eon™, were not commercially distributed until 2005. Based on the fact that Precision™ was commercially available on a very limited basis for the last six months of 2004, implantable rechargeable neurostimulators are not reflected in the current outpatient claims data, which captures dates of service from January 1, 2004 through December 31, 2004.

2. **Provides substantial clinical improvement.**
Rechargeable neurostimulators represent a significant clinical improvement over existing technology. Rechargeable technology provides more treatment options for those patients requiring high energy stimulation. Prior to the approval of rechargeable neurostimulators, patients with high energy needs often underwent frequent neurostimulator replacement or they were unable to experience the full benefit of neurostimulation due to battery conservation. Rechargeable technology provides for a reduction in surgeries related to neurostimulator replacement caused by battery depletion.

Additionally, physicians are able to use two 16-electrode leads instead of the 8-electrode leads used in older neurostimulators. By using leads with more electrodes, physicians can place the leads so that more coverage is provided to the spinal nerves. This also provides for the option to reprogram the neurostimulator if a lead migrates after implantation, thereby avoiding an invasive surgery for lead revision.

Medtronic device registry data has demonstrated that 34% of patients aged 54 and older, who receive non-rechargeable devices, require replacement surgery within 10 years of implant. More than half of those patients have high energy needs that deplete the battery within the first three years. As previously stated, rechargeable technology provides for the avoidance of these battery replacement surgeries. Additionally, it has

been demonstrated that patient compliance is vastly improved with rechargeable technology.

In closing we appreciate your consideration of our comments and respectfully request that CMS consider the information provided in this letter as well as information previously submitted, to qualify rechargeable neurostimulation technology for the establishment of a new device category eligible for pass-through payment in the hospital outpatient setting. Questions or requests for additional information should be directed to Marilyn Halseth at (763) 505-0277.

Respectfully,

Marilyn Halseth

Marilyn Halseth
Reimbursement Manager
Medtronic Neurological
710 Medtronic Parkway NE
Minneapolis, MN 55423

Attachment 4

Hospital Outpatient Prospective Payment System Proposed Rule [CMS-1501-P] Update for Calendar Year 2006

September 16, 2005

Agenda

- Introductions
- ICDs
- LV Lead
- Neurostimulators
- Infusion Pumps
- Electrode Reconfiguration
- Category Proposal
- Surgical Insertion
- New Tech APC/CPT Application
- Recommendations

Overall Issues

- Although some improvement is seen in the 2004 data, significant issues continue to persist with the quality of claims data, especially for services involving high-cost technologies
- Some variation in cost is expected from year to year, but a 15% downward reduction is not expected nor appropriate in claims data for devices that have been under represented historically
- We continue to seek solutions and look to CMS for their leadership in convening a broad stakeholder panel to continue to address these issues

Hospital Claims Data Issues

Issues with Charge Compression

- When determining costs, CMS assumes that hospitals mark up the cost of each service within a specific department by the same percentage
- However, as the GAO, MedPAC, and CMS have acknowledged, in practice, hospitals apply a lower mark-up to high-cost devices causing a systematic under representation of true costs or "charge compression"

ICD Procedures -- Proposed Rates Result in Hospital Losses of $4,000 or More Per Case

APC 0107

Median device costs:	$18,402[1] - $20,819[2]
Procedural costs[3]:	+ $1,335
Total Cost / Case:	$19,737 - $22,154
2006 Proposed Payment:	- $15,431
Total Loss / Case:	**$4,306 - $6,723**

APC Advisory Panel Recommendation – August 2005

The Panel recommends that for 2006, CMS base the payment rates for APCs 107 and 108, which provide payments for cardioverter defibrillator implantations, on their 2005 payment rates plus 3.2

percent.

Left Ventricular Lead – CPT 33225

•LV lead implant (33225) has been moved from New Technology APC 1525 with a status indicator 'S' to a clinical APC 0418 with a status indicator 'T'
•Clinical homogeneity is established with the APC change, but status indicator 'T' does not recognize that the major portion of the costs associated with the procedure (the lead itself) is not reduced regardless of the other procedures performed in conjunction with the lead implant
•LV lead implant also requires a different procedural aspect and approach than the primary procedures (33208 & 33249).
•Physician billing recognizes the differences in approach by classifying 33225 as an add-on code, not subject to multiple procedure reductions
•Under proposed status indicator, stand alone code (33224) would be overpaid

APC 0039 (Level I Implantation of Neurostimulator) Products – Medtronic (DBS), Cyberonics (VNS)

- APC Adjusted Median Cost $10,946
- 2006 Proposed payment $10,764

- IMS Health Average Device Cost[1] $10,635
- Procedural Cost[2] $ 2,543
- Estimated Costs to Hospital $13,178
- Difference from Proposed Payment ($ 2,414)

APC 0222 (Implantation of Neurological Device) Medtronic, ANS, ABC/Boston Scientific (Pain and Urinary Incontinence)

- APC Adjusted Median Cost $10,807
- 2006 Proposed payment $10,628

- IMS Health Average Device Cost[1] $11,370
- Procedural Cost[2] $ 1,709
- Estimated Costs to Hospital $13,079
- Difference from Proposed Payment ($ 2,451)

APC 0315 (Level II Implantation of Neurostimulator) Medtronic Dual Channel DBS (Kinetra)

- APC Adjusted Median Cost $17,538
- 2006 Proposed payment $17,247

- IMS Health Average Device Cost[1] $17,246
- Procedural Cost[2] $ 2,543
- Estimated Costs to Hospital $19,788
- Difference from Proposed Payment ($ 2,542)

APC 0227 (Infusion Pumps)

• APC "True" Median Cost	$ 8,236
• 2006 Proposed payment	$ 8,099
• IMS Health Average Device Cost[1]	$ 9,755
• Procedural Cost[2]	$ 1,532
• Estimated Costs to Hospital	$11,287
• Difference from Proposed Payment	($ 3,188)

Electrode APC Reconfiguration

August 2005 APC Panel Recommendations

Neurostimulator Electrode APCs Proposed Reconfiguration

The Panel recommends that CMS adopt the proposed reconfiguration of APCs 040 and 225 for neurostimulator electrode implantation as submitted by Medtronic, creating three APCs that are clinically homogenous and coherent in use of resources. As proposed, APC 040 would include CPT codes 63650, 64555, 64560, **64565** and 64561; APC 225 would include CPT codes 64553 and 64573; and a new APC would include CPT codes 64577, 64580, 64575, 64581, and 63655.

64565 was inadvertently omitted from the panel recommendation as posted on the CMS website, however, was part of the recommendation proposed and unanimously recommended by the panel.

Existing Device Category Criterion

CMS has proposed to revise Sec 419.66 (c) (1) of the regulation. This revision proposes to apply two tests based on their evaluation of information provided to them in the device category application.

- An applicant must show that the device is not similar to devices (including predicate devices) whose costs are already reflected in the claims data.
- An applicant must demonstrate that utilization of their device provides a substantial clinical improvement for Medicare beneficiaries compared with currently available treatments.

Medtronic fully supports this proposal and urge CMS to finalize.

Rechargeable Neurostimulator-

Pending Pass-Through Application

- It is not similar to devices whose cost is currently reflected in outpatient claims data.
  - Affected APC 0222
    Devices currently included –single and dual channel non-rechargeable neurostimulators, Radio Frequency non-rechargeable neurostimulators
  - Rechargeable neurostimulators are distinctly different from previous devices
    - » **Rechargeable – internal power source that is rechargeable; recharging only required for short period every 3-6 weeks; therapy can be provided to the patient 24/7; high patient compliance. Earliest FDA approval was April 2004.**
    - » Radio Frequency – external power source; not rechargeable; therapy ceases immediately when transmitter removed from implant site; low patient compliance (i.e., skin breakdown)
    - » Non-rechargeable – internal power source that must be surgically removed and replaced upon

battery depletion; therapy can be provided to the patient 24/7

Rechargeable Neurostimulator

- Provides substantial clinical improvement.
  - Rechargeable neurostimulators represent a significant clinical improvement over existing technology
  - Inpatient New Tech Add-On Payment approved which found substantial clinical improvement criteria met
  - Medtronic device registry data has demonstrated that 34% of patients aged 54 and older, who receive non-rechargeable devices, require replacement surgery within 10 years of implant.
  - More than half of those patients have high energy needs that deplete the battery within the first three years.
  - Rechargeable technology provides for the avoidance of these battery replacement surgeries.
  - It has been demonstrated that patient compliance is vastly improved with rechargeable technology.

Surgical Insertion

By way of implementation, CMS proposes to modify the current interpretation of regulations § 419.66(b)(3) to consider devices pass-though eligible if inserted or implanted through a natural or surgically-created orifice within the scope of surgically implanted devices, as well as those that are inserted or implanted through a surgically created incision. While this interpretation resolves the need to establish the existence of a traditional surgical incision to insert/implant a device through an orifice, we suggest that regulatory language be modified to institutionalize this change. Current language reads:

Sec. 419.66 Transitional Pass-through Payments

(b)(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted whether or not it remains with the patient when the patient is released from the hospital.

We request consideration to change the regulation to read:

(b)(3) The device is an integral and subordinate part of the service furnished, is used for one patient only, comes in contact with human tissue, and is implanted or inserted, through a natural or surgically created orifice or through a surgically created incision, whether or not the device remains with the patient when the patient is released from the hospital.

New Technology APC / CPT Application Requirement

- CPT application requirement will add undue delay in the dissemination of new technologies
  - Requires manufacturers and speciaty societies to apply for code before sufficient evidence is available, potentially leading to the assignment of a Category III code, which are not well accepted by payers
  - Timelines for CPT and New Tech application processes do not coincide well and do not allow for the clarity that CMS is seeking regarding the CPT Editorial Panel's consideration of the new technology
  - CPT Editorial Panel is a private organization and is not subject to the procedural protections necessary for public policy decision-making.

Recommendations

- Short Term
  - Base 2006 Payments on 100% of 2005 rates plus the hospital update
    - APCs 0107, 0108, 0039, 0222, 0227, 0315
  - Reconfigure APCs 0225 and 0040 as proposed including creation of new APC
  - Maintain a status indicator 'S' for the LV lead implant procedure
  - Modify category criteria as proposed
  - Modify regulatory language to institutionalize change to interpretation of pass-through eligibility for devices implanted through natural or surgically created orifices
- Long Term
  - Convene a broad stakeholder panel including hospitals, manufacturers, providers and others to consider the options and develop a solution

Attachment *5

Meeting of the Advisory Panel on Ambulatory Payment Classification (APC) Groups

Implantation of Neurostimulator Electrodes
APCs 0040 and 0225
July 17-19, 2005
Bonnie Handke, RN, Medtronic, Inc
On Behalf of Advanced Bionics, Advanced Neuromodulation Systems and Medtronic, Inc

Financial Disclosure

- I am an employee and stockholder of Medtronic, Inc.
- Medtronic is one of three companies that creates the products that are the subject of this presentation.

Description of Issue

- 2006 NPRM reconfigurations of APC 0040 and APC 0225
  - Specifically – movement of CPTs 63655 and 64580 to APC 0040 from APC 0225
- Impact
  - APCs not clinically cohesive
  - APCs not cost cohesive
    - Violation of two times rule
  - Results in 72.7% payment decrease for these CPTs

Clinical Description of the Service

- Percutaneous Lead Implantation
  - Typically performed by anesthesiologist
  - Electrode is same diameter as thin, guide-wire controlled, catheter-like lead and has circumferential metal contacts
  - Inserted percutaneously, through a specially designed spinal needle into epidural space
  - Less invasive procedure = lower risk to patient
  - Less effort by physician (RVU = 6.74)
  - Less expensive than laminectomy electrode

Clinical Description of the Service

- Lead Implantation with Laminectomy
  - Typically performed by neurosurgeon or orthopaedic surgeon
  - Electrode is wider than the lead and paddle-shaped with flat, plate-type metal contacts
  - Spinal ligaments and lamina removed to allow for passage of

electrode into epidural space
- Invasive procedure = higher risk to patient
- Significant effort by physician (RVU = 10.29)
- More expensive than percutaneous electrode

NPRM 2006 APC 0040 CPT Assignment

- APC 0040 – Proposed Payment $3,268 (Median cost $3,338)
  - 63650 - Implant electrode-perc-spinal
    - **Accounts for 62.7% of claims used in rate setting**
    - **Median cost $2,866**
  - 64555 - Implant electrode-perc-peripheral
  - 64560 - Implant electrode-perc-autonomic
  - 64561 - Implant electrode-perc-sacral
  - 64565 - Implant electrode-perc-neuromuscular
  - 64575 - Implant electrode-incision-peripheral
    - **Median cost $5,815**
  - 64581 - Implant electrode-incision-sacral
    - **Median cost $5,501**
  - 63655 - Implant electrode-lami-spinal
    - **Median cost $5,746**
  - 64580 - Implant electrode-incision-neuromuscular
    - **Median cost $3,362.**

NPRM 2006 APC 0225 CPT Assignment

- APC 0225 - Proposed Payment - $13,865 (Median Cost $14,162)
  - 64553 - Implant electrode-perc-cranial
    - Median cost $12,064
  - 64573 - Implant electrode-incision-cranial
    - Median cost $14,510
  - 64577 - Implant electrode-incision-autonomic
    - Median cost $11,312

Recommendations and Rationale for Change

- Recommendations
  - Reconfigure proposed APCs 0040 and 0225 to reflect percutaneous and cranial lead procedures, respectively
  - Create a third APC to reflect lead procedures that require incisions or laminectomies
- Rationale
  - Eliminate two times violation
  - APCs will be clinically and cost cohesive

Recommendations:
Alternative 2006 APC Reconfigurations
Consequences of No Change

- Creates inappropriate financial incentives without regard to

medically appropriate care

- Barriers to access if payment rates are inadequate
- APCs are not clinically and cost cohesive
- Laminectomy/Incision for implantation of electrodes subject to inappropriate 72.7% payment decrease

Recommendations: Summary

Attachment #6 -

Meeting of the Advisory Panel on Ambulatory Payment Classification Groups

Insertion ICD Pulse Generator & Insertion of ICD System // APCs 0107 & 0108

August 17 - 19, 2005

Presented by
Bob Thompson, M.S., M.A.
Director, Reimbursement, Economics & Health Policy
Medtronic, Inc.
On behalf of Medtronic, St. Jude Medical and Guidant

Financial Disclosure

- I am an employee and stockholder of Medtronic, Inc.
- Medtronic is one of three companies that creates the products that are the subject of this presentation.

HCPCS Codes & APCs Affected

- G0297: Insertion of single chamber pacing cardioverter defibrillator pulse generator
- G0298: Insertion of dual chamber pacing cardioverter defibrillator pulse generator

- G0299: Insertion or repositioning of electrode lead for single chamber pacing cardioverter defibrillator and insertion of pulse generator
- G0300: Insertion or repositioning of electrode lead(s) for dual chamber pacing cardioverter defibrillator and insertion of pulse generator

Clinical Description of the Service
Implantation of the Implantable Cardioverter Defibrillator Pulse Generator Only

- Implantation of the implantable cardioverter defibrillator (ICD) is normally performed as part of an ICD replacement procedure. The overall procedure involves two APCs (0105 and 0107)
- An incision is made, the leads are disconnected from the existing ICD and the device is removed (APC 0105)
- The leads are connected to the new ICD and the device and lead functions are tested. The new ICD is then inserted, the incision is closed, and the device therapies are programmed (APC 0107)

Clinical Description of the Service
Implantation of the Implantable Cardioverter Defibrillator System

- Implantation involves the surgical placement of the ICD pulse generator and the placement of pacing or defibrillation lead(s) in the right atrium and/or right ventricle (APC 0108)
- The leads are connected to the ICD and the device and lead functions are tested. The ICD is then inserted, the incision is closed, and the device therapies are programmed (APC 0108)

Proposed Payment Rates Result in Significant Hospital Losses

- Prior to the publication of the 2006 proposed rule, industry representatives met with CMS and presented third-party device acquisition cost data
- 2006 proposed payment rates clearly show that CMS did not incorporate the data provided, as the rates are significantly less than device acquisition costs and represent a 14.5% reduction over last year and a 16.8% reduction over the last two years
- Hospital losses for APCs 0107 and 0108 may jeopardize patient access to life-saving devices in the outpatient setting and encourage hospitals to move procedures to a setting that is less

cost-effective

Proposed Rates Result in Losses of $4000 or More Per Case

APC 0107

Median device costs:	$18,402[1] - $19,029[2]
Procedural costs[3]:	+ $1,335
Total Cost / Case:	$19,737 - $20,364
2006 Proposed Payment:	- $15,431
Total Loss / Case:	**$4,306 - $4,933**

- CY 2004 claims data continue to inadequately represent device acquisition costs due to issues with coding accuracy and charge compression
- This has been a recurring problem since the inception of OPPS
- Requiring C-codes may improve the median costs for 2007, but charge compression will still remain an issue for high cost devices

Issues with Charge Compression

- When determining costs, CMS assumes that hospitals mark up the cost of each service within a specific department by the same percentage
- However, as the GAO, MedPAC, and CMS have acknowledged, in practice, hospitals apply a lower mark-up to high-cost devices causing a systematic under representation of true costs or "charge compression"

Recommendations

- We request that the APC Advisory Panel recommend the following to CMS:
  - 2006
    - Base the final payment rates for APC 0107 and 0108 using 2005 payment rates plus the OPPS hospital update (3.2%)
  - 2007 and beyond
    - Address charge compression issues
    - Consider external data when necessary to establish payment rates until claims data are adequate and can be used in rate-setting

Device Acquisition Cost Data for APCs 0107 and 0108

CMS-1501-P-494

Submitter : Ms. Jana Rupp **Date:** 09/15/2005

Organization : Kalispell Regional Medical Center

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-494-Attach-1.DOC

KALISPELL REGIONAL
MEDICAL CENTER

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Proposed Nonrecurring Policy Changes for "Multiple Diagnostic Imaging Procedures" published in the July 25, 2005 Federal Register

Quoted from July 25, 2005 Federal Register: "When multiple images are acquired in a single session, most of the clinical labor activities are not performed twice... we (CMS) consider that the following clinical labor activities included in the "technical component" of the MPFS are not duplicated for subsequent procedures: Greeting, positioning and escorting the patient; providing education and obtaining consent; retrieving prior exams; setting up the IV; and preparing and cleaning the room."

Comment: We disagree with the statement that those duties listed make up most of the clinical labor. The functions specific to exam protocol (i.e. interactively scanning the areas of interest under Ultrasound, prescribing CT and MRI slices and sequences, image processing, archival, monitoring patient disposition, etc.) greatly outweigh those listed duties both in time and correlation to exam quality. Also, those duties outlined in the quote above are done differently if not *absolutely* duplicated in the case when multiple exams are acquired in a single session. For instance, positioning is done differently based on imaging multiple areas; the IV set up is often different, requiring more contrast material to be drawn up; the education and preparation is specific to the areas of interest and are therefore more comprehensive; retrieving prior exams requires more attention and likely will mean more exams retrieved; and specific to Ultrasound, each area scanned often requires a transducer change and cleaning process, or specific to MRI, there may be a coil change that equates to a new patient setup.

Further, most of the clinical labor duties outlined above which are not duplicated when performing multiple exams such as greeting, escorting the patient, retrieving prior exams; preparing and cleaning the room, etc, are performed by non-clinical staff, i.e. aides.
By assuming that most of the clinical labor is outlined by those duties, you equate technical time to non-technical time. The modalities of Ultrasound, CT and MRI demand highly trained technologists as well as the purchase and maintenance of very expensive equipment. Equating the functions of an aide (greeting, escorting, etc.) to the functions of a technologist and the operation of sophisticated, million-dollar equipment is insulting and clearly misunderstood in terms of the value and correlation to exam quality.

As stated in the proposed rule, "Appropriate diagnostic evaluation of many constellations of patients' signs and symptoms and potentially affected organ systems may involve assessment of pathology in both the abdomen and pelvis, body areas that are anatomically and functionally closely related. Therefore, both studies are frequently performed in the same session to provide the necessary clinical information to diagnose and treat a patient." This statement is precisely why there is *equal* value to both exams, and further is the most appropriate thing to do in terms of patient care and/or disease management. Proceeding with the proposed rule will create a backlash of poor patient care and/or disease management when institutions and/or practitioners choose to scan areas on separate days, wholly for the purpose of not taking a reimbursement reduction. Another point to ponder is that any individual exam requires documented medical necessity and is done so for each exam ordered and performed. Should second and subsequent exams not be required to be documented as medically necessary then if the value has been reduced by 50%?

In summary, the premise that any single exam's value is the sum of the associated "costs" is shortsighted. We don't believe that we are being paid a technical fee for greeting and escorting a patient. The worth of the exam is in the exam itself. If the patient were to walk, unassisted directly into the exam room, the technical charge would and should be no different than if a technologist had to transport the patient by gurney or by wheelchair, assist the patient in going to the bathroom or bedpan, and/or having several technologists assist an obese patient transfer. The methods leading up to the exam (greeting patient, escorting, providing education, etc.) are the choice of the institution performing the exam and are highly variable depending on the institution. The technical exam performed should be reimbursed for the value of that exam. When you purchase two pairs of shoes, you pay for two pairs not one and a half, no matter how many you try on in the store.

Respectfully submitted,

Jana Rupp, R.T. (R) (MR)
Imaging Services Director
Kalispell Regional Medical Center
310 Sunnyview Lane, Kalispell MT 59901

Submitter : Mr. Eric Meier
Organization : Calypso Medical
Category : Device Industry

Date: 09/15/2005

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-1501-P-495-Attach-1.PDF

CALYPSO MEDICAL

September 15, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Proposed Changes to the OPPS Payment System and 2006 Payment Rates

Issue: New Technology APC

Dear Dr. McClellan:

Calypso Medical Technologies is pleased to submit these comments to the Centers for Medicare and Medicaid Services (CMS) in response to the July 25, 2005 *Federal Register* notice regarding the 2006 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule.

We would like to thank CMS for the opportunity to make recommendations regarding the proposal to require the submission of a CPT code application as part of the New Technology APC criteria.

New Technology APCs
CMS proposes to require that an application for a code for a new technology service be submitted to the American Medical Association's (AMA) CPT Editorial Panel before CMS will accept a New Technology APC application for review. Furthermore, CMS is proposing that a copy of the submitted CPT application be submitted to CMS as a part of the application for a New Technology APC. CMS is also proposing to require a letter from the AMA acknowledging the CPT code application.

Calypso Medical Technologies is concerned that the AMA CPT Editorial Panel may not be an appropriate forum for a federally mandated new technology decision. This requirement may add unnecessary delay of new technology to Medicare beneficiaries preventing rapid availability of new technology as intended by the MMA legislation.

The AMA CPT Editorial Panel is a private organization, utilizing closed processes that are not subject to procedural protections typically required for public policy. AMA meetings are closed to the public and the bases for decisions are not available to the public, including hospitals and physicians. The AMA CPT Editorial Panel allows no participation or representation from the medical technology industry and manufacturer community. Further, the panel is not subject to the protections of the Administrative Procedures Act, the Freedom of Information Act, or the Federal Advisory Committee Act.

Clearly, the requirement of the submission to the AMA CPT Editorial Panel would require involvement of an organization that may not be accountable as are all other agencies that are subject to federal public policy decisions.

The requirement to submit New Technology APC applications together with CPT code applications presents an inherent conflict of purpose. By definition, category I CPT codes are assigned to procedures that have become an accepted standard of care and are in widespread use. This conflicts with and, in fact, defeats the purpose of creating a special coding vehicle (new technology APCs) to facilitate adoption and dissemination of new technology and the collection of clinical data. If manufacturers are forced to apply for a CPT code before widespread use or extensive information about the technology is available, it is likely that the CPT Editorial Panel would assign a Category III (emerging technology) code. This often results in a non-coverage decision by local Medicare carriers and fiscal intermediaries and many commercial payers thus denying Medicare patients access to technology. The end result of the proposed rule would be a disincentive for manufacturers, particularly smaller ones, to innovate and market novel and beneficial medical technologies.

If the AMA CPT Editorial Panel were to agree to open its meetings to the public, place voting representatives from manufacturers on the decision making panel and offer additional concerned parties the opportunity to participate, comment, and otherwise comply with the Administrative Procedures Act, Freedom of Information Act, and Federal Advisory Committee Act, then the proposed role of the AMA would more likely support continued rapid access of new technologies to Medicare patients. Until this time we recommend that CMS eliminate the proposed requirement that manufacturers submit a CPT application prior to submission of a New Technology APC application to CMS.

New technology continues to offer important treatment for Medicare patients. Appropriate and timely payment for new technologies permit Medicare beneficiary's full access to the same high quality care in the hospital outpatient setting realized by patients covered by private insurance.

We hope that CMS will take these issues under consideration during the development of the HOPPS Final Rule and eliminate the proposed requirement for a CPT application submission prior to the New Technology APC application.

Should CMS staff have additional questions, please contact me either via email at emeier@calypsomedical.com or telephonically at (206) 774-4205.

Sincerely,

Eric R. Meier
President and CEO

CMS-1501-P-496

Submitter : Jerry Stringham **Date:** 09/15/2005

Organization : Medical Technology Partners, Inc.

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-1501-P-496-Attach-1.PDF

September 15, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1501-P
P.O. Box 8016
Baltimore, MD 21244-8018

Re: Comment on OPPS Proposed Rule – Vascular Access Procedures

Dear CMS:

Medical Technology Partners, Inc. is submitting this comment in support of the proposed reassignment of vascular access procedures into more clinically appropriate APCs. Because CMS now has cost and utilization data available to assess APC assignments for the recently revised vascular access section of CPT, and the APC Panel has supported the proposed reassignments and recommendations, we agree it is appropriate, at this time, to make the APC modifications described in Table 13 of the Proposed Rule and to leave all vascular access codes as assigned in the proposed rule.

We also agree that it is appropriate to create new APCs 0621 (Level I Vascular Access Codes), 0622 (Level II Vascular Access Codes), and 0623 (Level III Vascular Access Codes) in order to facilitate procedure assignment based on median cost and clinical homogeneity in cases where legitimate median cost (subject to correct coding) claims are available.

Thank you for your efforts in improving APCs associated with vascular access procedures.

Sincerely,

Jerry Stringham

Jerry Stringham
President

15200 Shady Grove Road, Suite 350, Rockville, Maryland 20850 • 301-296-4334 • (f) 443-583-2476

Vascular Access Codes

36555
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CMS-1501-P-497

Submitter : Rochelle Augspurger **Date: 09/15/2005**

Organization : BroMenn Center for Wound Healing and HBO

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

I am submitting this public comment to bring to your attention an error in the proposed rule, CMS-1501-P, ?Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2006 Payment Rates? relating to the payment rates for the wound-healing products Apligraf (C1305) and Dermagraft (C9201). These products have been paid in the hospital outpatient prospective payment system as specified covered outpatient drugs and should continue to be paid in 2006 similar to other such drugs. Patient access to these important products is jeopardized by the payment rates in the proposed rule. We respectfully request that the payment rates for Apligraf and Dermagraft be corrected in the final rule. Apligraf and Dermagraft are unique living human tissue substitutes for the treatment of chronic ulcers. Randomized prospective clinical trials have demonstrated the efficacy of these products to accelerate and support healing of chronic diabetic foot ulcers (Apligraf and Dermagraft) and venous leg ulcers (Apligraf) preserving and improving the quality of life of thousands of diabetics and other elderly patients who suffer from chronic leg and foot ulcers. Many of these patients would have had to undergo limb amputations without the benefits of Apligraf and Dermagraft. In the proposed Hospital Outpatient Rule for calendar year 2006 the Centers for Medicare and Medicaid Services proposed to pay specified covered outpatient drugs at average sales price (ASP) plus six percent for the acquisition cost of the drug. The rule proposes to pay a pharmacy overhead charge of an additional two percent which results in a total payment for specified covered outpatient drugs of ASP plus eight percent. In 2002 both Apligraf and Dermagraft were paid as a biological under the pass through list. Following the enactment of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, both products have been paid for as sole-source biologicals in 2004 and in 2005 under the specified covered outpatient drug provision. Both products were included in the General Accountability Office (GAO) survey of acquisition costs for specified covered outpatient drugs dated June 30, 2005 (GAO-05-581R). The GAO report included the relevant ASP rates for each product. However, in the proposed rule both Apligraf and Dermagraft would be incorrectly paid based on rates derived from claims data in stead of payment at ASP plus eight percent. Although the proposed rule is intended to provide reimbursement of ASP+8% for covered products, in the case of Apligraf and Dermagraft, the reimbursement rate is proposed to be 30% below the selling price of the product. Accordingly, both products experienced a significant decrease in payment: Apligraf -- 2005 outpatient rate $1,130.88; 2006 proposed outpatient rate $766.84 and Dermagraft -- 2005 outpatient rate $529.54; 2006 proposed outpatient rate $368.32. There may have been some confusion in the proposed rule because the products are reimbursed in the physician?s office under codes with different descriptors. In the physician office setting, Apligraf and Dermagraft have been paid based on the ASP + six percent methodology under J7340 (Metabolic active Dermal/Epidermal tissue) and J7342 (Metabolically active Dermal tissue) respectively. I petition CMS to correct the error in the proposed ruling and ensure that Apligraf and Dermagraft are reimbursed as a specified covered drug, at ASP+8%. Thank you for your attention to this issue, and I look forward to working with you to correct the issue in the final rule.

Submitter : Dr. Barry Hirsch **Date:** 09/16/2005

Organization : Univer. of Pittsburgh Medical Center

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

The anticipated reduction in reimbursement for cochlear implants to medicare recipients will have significant impact on our older patients. People who become profound deaf are restricted from the quality of life they once had. They are unable to communicate with family and people in their environment. The support CMS has provided to date has had phenomenal impact on thousands of people allowing them to be in the mainstream of life. The proposed cut in reimbursment will truly make it financially impossible for hospitals and clinics to offer these most important services to this sector of our population. I urge CMS to use accurate external device cost data to evaluate the relative weight of APC 0295. Keep the payment at 100% of the 2005 payment rate and consider inflation and other update factors towards this APC. I am truly concerned that this reduction will have a significant negative impact on so many people. This reduction will likely preclude older idividuals from these services. This would limit the number of implant centers due to cost restraints and curtail the number of implants done in our country. You really need to directly hear from people as individuals to see the impact on the quality of their lives. This is not a one time fix but something that should provide hearing for the rest of their lives.